

**A RETROSPECTIVE STUDY ON CLINICAL TEST BATTERY FOR
PERSONS WITH NORMAL HEARING HAVING TINNITUS: BRIDGING
THE GAP FROM RESEARCH TO CLINICAL PRACTICE**

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September, 2021

Certificate

This is to certify that this dissertation entitled “**A retrospective study on clinical test battery for persons with normal hearing having tinnitus: bridging the gap from research to clinical practice**” is the bonafide work submitted as part of fulfilment for the Degree of Masters of Science in Audiology of the student with Registration No. 19AUD037. This has been carried out under the guidance of a faculty of this institute and has not been submitted earlier to any other Universities for the award of any other diploma or degree.

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Declaration

This dissertation entitled “**A retrospective study on clinical test battery for persons with normal hearing having tinnitus: bridging the gap from research to clinical practice**” is the result of my own study under the guidance of Dr. Animesh Barman Professor in Audiology, All India Institute of Speech and Hearing and has not been submitted earlier to any other Universities for the award of any other diploma or degree.

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Chapter 1

INTRODUCTION

The word tinnitus originated from the Latin word “tinnire,” meaning ringing or tingling like bell. It is one of the common otological complaints reported worldwide. Tinnitus is the perception of the sound when no external sound is present (ASHA, 2005). (Jastreboff & Hazell, 1993) defined tinnitus as the perception that results exclusively from the activity within the auditory nervous system, in the absence of corresponding mechanical or vibrational activity inside the cochlea, and is not related to external stimulation of any kind. Tinnitus is also defined as the conscious perception of sound originating involuntarily in the head of the individual (McFadden & National Research Council (U.S.). Working Group 89., 1982). Various definitions of tinnitus have been proposed based on the type of sound, the origin of the sound, psychoacoustical properties of sound, the severity of sound, pathophysiology and aetiology. In general, tinnitus is the continuous or intermittent ringing of the sound in one or both ears lacking an external acoustic stimulation. Some patients hear multiple sounds. For some, the sound quality remains constant, whereas, for others, it keeps changing. It can take the form of any sound ranging from ringing, hissing, buzzing, whistling, roaring, clicking, tonal, or noise. Perception of sound can be continuous or intermittent. It can be pulsatile (synchronous/nonsynchronous to heartbeat) or non-pulsatile. It can be heard in one ear (unilateral), both ears (bilateral) or inside the head (intracranial) (Cima et al., 2019). Tinnitus can be objective or subjective (Langguth Langguth, Kreuzer, Kleinjung & Ridder, 2013; Møller, 2011a; McFadden, 1982). Objective tinnitus is audible by the person experiencing it and also by the examiner (Roberts, Eggermont, Caspry, Shore, Melcher & Kaltenbach, 2010). Subjective tinnitus is when the sound is audible only to

the person experiencing it (Jastreboff, 1990). Subjective tinnitus is a solely electrochemical phenomenon, whereas objective tinnitus is the sense of genuine, mechanical sounds originating within the body (somatosound) (Hertzano, Teplitzky & Eisenman, 2016). Subjective type of tinnitus is reported more frequently. Subjective tinnitus is a complicated phenomenon with multiple causes. As a result, a wide range of patient characteristics with a heterogeneous clinical profile is commonly found in individuals experiencing tinnitus.

Tinnitus is a prevalent phenomenon. Almost every person at some point has experienced mild, temporary ringing in their ears. Tinnitus is the third most common otological symptom after hearing loss and vertigo (Pajor, Ormezowska & Jozefowicz, 2013). The prevalence of tinnitus in the United States (US) is 1 in 10 adults (Bhatt, Lin & Bhattacharyya, 2016). The prevalence of tinnitus worldwide has been reported to be ranging from 5.1% to 42.2% (McCormack, Edmondson, Somerset, and Hall, 2016). These disparities in prevalence are due to differences in the definition of tinnitus, the age of the participants, and the study design. The most extensive survey of tinnitus prevalence in the United Kingdom (UK) was conducted as part of the National Study of Hearing in England, surveying 48,313 people. Tinnitus was reported to be experienced by 10.1 percent of participants in this study, with 2.8 percent describing their symptoms as at least moderately annoying. Tinnitus had a significant impact on the ability to perform daily activities for 0.5 percent of respondents (McFerran, Hoare, Carr, Ray & Stockdale, 2018). The prevalence of tinnitus in India is around 9.6% (Sreeraj et al., 2013). In South India, 29.3% of the participant reported tinnitus as the primary complaint. The percentage of participants reporting tinnitus increased with age above 40 years (Manche, Madhavi & Meghanadh, 2016).

Tinnitus can be reported as the only symptom, or it can be reported with various other otological and non-otological conditions. According to a national study conducted by the Public Health Agency of America in 1984-1985, severe tinnitus is perceived as the third-worst symptom in humans, owing to the pain and untreatable dizziness associated with it. Tinnitus perception has also been found to be strongly related to emotional impact. Tinnitus can be extremely bothersome and even have a negative impact on quality of life, such as disrupted sleep cycles, anxiety, irritability, concentration difficulties, depression, communication issues, or in the most severe cases, suicidal thoughts or actions. Clinical research on tinnitus patients suggests that psychological variables influence its origin and perception. Tinnitus perception is due to two processes: the phantom perception of a sound in the ears or head and the emotional response to that perception. Evidence confirms that adverse psychological reactions such as cognitive impairments, negative emotions, and disordered attentional processes are essential in developing severe tinnitus (McKenna, Handscomb, Hoare & Hall, 2014). Many people with tinnitus can cope with it; only one in every five is reported to have emotional symptoms, and 7.5% of them are so severely impaired that it interferes with their day-to-day functioning. This disparity in severity suggests a partial dichotomy between the mechanisms that generate the tinnitus-related signal and those that cause tinnitus distress (Henry & Manning, 2019).

Tinnitus is a symptom, not a disease. It is tough to identify the etiology and pathophysiology of tinnitus because there is no uniform animal model to explore. Also, there is no objective method for determining whether or not tinnitus (subjective type) is actually present (Mckee & Stephens, 1992). While there are various models for the perception of tinnitus, no single theory or model can thoroughly explain tinnitus's pathophysiology. Tinnitus is generally thought to be because of loss of input to the

central auditory system from the peripheral auditory system (Henry et al., 2014; Schaette & McAlpine, 2011). Many experts believe that tinnitus can be caused by a combination of simultaneous and sequential reasons, such as acoustic trauma, ototoxic medicines, hearing loss, vascular or metabolic issues, tumours, Meniere's disease, and perilymphatic fistula, to name a few (Henry, Dennis & Schechter, 2005). Noise exposure is also found to be a good predictor of tinnitus (Shargorodsky et al., 2010a). Changes in the inner ear are thought to be responsible for 90 percent of tinnitus occurrences (Halls, 2013). Tinnitus is strongly associated with various degrees of hearing loss, but tinnitus can also occur with normal hearing. Studies have reported that 85 to 96% of people with tinnitus have different degrees of hearing loss, and 8 to 10% have hearing sensitivity within normal limits (Barnea, Attias, Gold & Shahar, 1990). The perception of tinnitus with hearing loss is widely attributed to the central auditory system's neuroplastic changes. The abnormal tympanic membrane, noise exposure from earphones, noise exposure at the workplace, noise exposure outside the workplace, and brief noise exposure all can lead to tinnitus (Kim et al., 2015).

In the tinnitus with the normal hearing group, the presence of tinnitus in isolation or in association with various otological symptoms (vertigo, difficulty understanding speech in noise, ear pain, itching sensation, hyperacusis) suggests that it may be a primary symptom of diseases that could be diagnosed later, only after the onset of hearing loss. Some studies suggest that tinnitus cannot exist without hearing loss. In tinnitus with normal hearing, the hearing loss is undiagnosed due to low audiometric resolution or the failure to test ultra-high frequencies (Searchfield, Jerram, Wise & Raymond, 2007). The presence of tinnitus in persons with normal conventional audiometric threshold could be explained by generalized damage up to 30% of the outer hair cells across the spiral of the cochlea, with no impairment to the hearing threshold

at frequencies between 250 Hz and 8 kHz (Valente, Carvalho, Mezzalira, Stoler & Paschoal, 2012).

In persons with normal hearing, tinnitus indicates underlying impairment in cochlear or neural functioning at various auditory levels and might suggest a hidden and subclinical otological problem (Henry, Roberts, Caspary Theodoroff & Salvi, 2014). One of such hidden causes was suggested to be cochlear synaptopathy or deafferentation, which refers to problems in the synaptic connections between inner hair cells and type I auditory nerve fibers. Tinnitus patients with normal audiometric thresholds are reported to have the presence of deafferentation (Weisz et al., 2007). The deafferentation of a substantial fraction of the auditory nerve (AN) fibers could trigger the development of a neural correlate of tinnitus in central auditory structures (Schaette & McAlpine, 2011). Mice exposed to mild acoustic trauma showed a temporary shift in hearing thresholds but permanent deafferentation of 50–60% of the AN fibers in the high-frequency region of the cochlea, demonstrating that normal hearing thresholds do not always indicate the absence of cochlear damage (Kujawa & Liberman, 2009). Regardless of peripheral deafferentation, central disinhibition could also cause tinnitus in subjects with normal hearing (Weisz et al., 2007).

On the other hand, tinnitus can also occur in the absence of any discernible auditory deficits. There is a possibility of severe tinnitus without any sign of aural disease (Makar, 2021). Tinnitus has been linked to several comorbidities due to a variety of pathophysiological factors. (Choi, Lee & Kim, 2021). Multiple associated factors have been identified, including cardiovascular, psychological, neurological, musculoskeletal, and dietary factors (Deklerck, Debacker, Keppler & Dhooge, 2020). Tinnitus involves both psychoacoustic and psychological aspects (Martines, Bentivegna, Piazza, Martines, Sciacca & Martinciglio, 2010). Tinnitus sufferers have

a higher inclination to neurotic personality features (Mckee & Stephens, 1992). Anxiety and depression are common pathologies in tinnitus patients. The relationship between major depression and tinnitus has been reported in 48-60% of cases, and the severity of depression and anxiety is related to the severity of tinnitus (Pavaci et al., 2019). It is unclear if peripheral tinnitus produces secondary to psychological alterations or whether these characteristics precede and predispose to the onset of or complaint about tinnitus (Mckee & Stephens, 1992).

Tinnitus can result from multiple physiological causes (Baguley, 2002). In some people, the inputs of the somatosensory, somatomotor, and visual-motor systems can elicit or regulate tinnitus (Pavaci et al., 2019). Tinnitus is more common in females, those with a smoking history, those who reported less sleep (< 6 h), those who were more stressed, those who lived in smaller households, and those who had a history of hyperlipidemia, rheumatoid arthritis, osteoarthritis, asthma, depression, thyroid disease (Kim et al., 2015).

Researches have been conducted in the field of Audiology among individuals with normal hearing having tinnitus, reporting deviant findings in their auditory system at various levels (Sreeraj, 2017). Normal conventional pure tone threshold does not rule out cochlear or neural damage completely. There might be some hidden pathologies. Researchers have shown that many auditory tests such as Extended high-frequency audiometry (EHFA), DPOAE fine structure and contralateral suppression of fine structure DPOAE, psychophysical tuning curves (PTC), auditory brainstem response (ABR), and late latency response (LLR) have abnormal findings in persons with normal hearing having tinnitus compared to persons with normal hearing and no tinnitus (Sreeraj, 2017). There is a higher incidence of peripheral vestibular dysfunction in patients with tinnitus, even when no accompanying vertigo is reported (Seabra &

Diamantino, 1995). This warrants the need for complete cochleovestibular evaluation in persons with normal hearing having tinnitus. In addition to clinical history analysis, both quantitative (objective) and qualitative (subjective) measures can be used to assess tinnitus clinically. Quantitative measurements include psychoacoustic measurements, the most common of which are loudness and pitch measurements. Visual Analog Scales (VAS) and self-perception questionnaires are two of the most used qualitative instruments.

1.1 Need for the study

Tinnitus is a non-specific sign of disorder of the peripheral and/or central auditory system and the involvement of the non-auditory region of the central nervous system. This results in a diverse tinnitus population, which poses a significant challenge concerning diagnosis, prevention and treatment of tinnitus (Deklerck, Debacker, Keppler & Dhooge, 2020). The site, or more likely sites, of subjective tinnitus's onset differs from patient to patient, and identifying potential sites is a focus of significant research. In recent decades, efforts have been made to understand tinnitus pathology better and equip patients with specialized treatments (Cima et al., 2019; Langguth et al., 2013). Tinnitus is currently diagnosed based on a patient's testimony; there is no objective way to determine if tinnitus is present. The subjective nature of tinnitus makes the assessment of tinnitus a challenging task. There are a few but not so conclusive no well-defined standard guidelines for assessment, treatment and referral of persons with tinnitus. The heterogeneity in clinical profile hampers the development of uniform assessment and treatment strategies, with most currently proposed therapies demonstrating variable efficacy in this large patient group. This leads to poor management of persons with tinnitus. Most of the time, clinicians are unaware of the assessment and management procedure of persons with tinnitus, especially when

routine audiological evaluations are normal. This leads to prolonged suffering, increased emotional impact, negative counselling for persons with normal hearing having tinnitus.

As a result, despite their rarity, tinnitus with normal hearing patients constitutes a significant group due to the characteristics associated with tinnitus, rather than hearing loss, as in the other cases. A detailed audiological assessment is essential, along with medical and psychological evaluations for reliably assessing tinnitus. Audiologists play an essential role in the assessment procedure that helps to identify the type of tinnitus, carry out the behavioural and electrophysiological assessment, provide guidelines to support the diagnosis of the underlying pathology, and establish a reference point to plan management strategies.

Despite the increase in research on the various clinical tests and instruments for assessment, identifying pathophysiology, associated factors, and extensive description of psychoacoustic methods for the objective measurement of tinnitus, the clinical practice is highly variable (McCormack, Edmondson, Somerset, and Hall, 2016). The fact that for persons with normal hearing having tinnitus, there is a lack of effective standard clinical practice protocol, which is difficult to deny. The difficulty in measuring tinnitus and the limitation of better understanding of this symptom and its relationship with other factors make it challenging to evaluate the results of different types of treatment.

Researchers worldwide have found various tests (EHFA, OAE suppression, DPOAE fine structure, ABR measures) sensitive enough to identify the subclinical pathologies associated with normal hearing with tinnitus at cochlear and/or at the various levels of the auditory nervous system. However, the clinical utility of such tests remains limited, and many such tests are not used as part of a routine clinical test battery

for persons with tinnitus. Hence, there is a large gap between clinical practice and evidence-based research. So, there is a need to analyse various shortcomings between research outcome and clinical practice and propose a clinical assessment test battery for persons with normal hearing having tinnitus. The pathophysiological involvement of non-auditory structures and the potential impact of non-otologic treatment techniques underscore the need to elucidate the role of non-otologic elements in the development and maintenance of tinnitus (Deklerck, Debacker, Keppler & Dhooge, 2020).

During the assessment of tinnitus, the clinician must identify all relevant tinnitus-related factors. Tinnitus must be viewed as a result of a complicated interaction between various audiological and non-audiological factors. There has not been a comprehensive collection of all possible complaints. It would be interesting to identify the relation between tinnitus and associated factors in cases with normal hearing with tinnitus. Hence, the current study is undertaken to determine the audiological tests administered in the clinical setup and compare the protocol (audiological tests administered) and their results with that reported in the literature.

1.2 Aim of the study

The present study aims to retrospectively analyse the test battery used to assess the individuals with normal hearing having tinnitus in clinical practice and gathering signs, symptoms, and associated conditions of such patients. To compare all this information with the evidence-based audiological tests results reported in the literature and to suggest test protocol based on symptoms, if any.

1.3 Objectives of the study

1. To analyse the clinical evaluation protocol for persons with normal hearing sensitivity having tinnitus and determine the various tests administered as a part of the routine audiological evaluation.
2. To identify the associated conditions and their relationship with the tinnitus with the help of a detailed case history approach.
3. To compare the clinical protocol used for audiological assessment of individuals having tinnitus with normal hearing and the available evidence-based literature. Also, highlighting the limitations of the routine audiological tests carried out as a part of the test battery and its shortcomings to assess the hidden pathologies associated with tinnitus at the cochlear and/or nervous system level.
4. To propose test protocol/s based on clinical signs and symptoms and literature available for individuals with normal hearing having tinnitus.

Chapter 2

REVIEW OF LITERATURE

Tinnitus as a symptom has been documented several thousand years back (Jastreboff & Hazell, 2008). Hippocrates mentioned tinnitus in 400 BC (Maltby, 2012). Since then, tinnitus has been reported throughout the literature worldwide. Tinnitus is a prevalent condition affecting individuals of all ages, gender and ethnicity. Almost everyone once in a lifetime has experienced a momentarily and temporally ringing in the ear(s) in the general population (McFadden & National Research Council (U.S.) Working Group 89., 1982). Research has been carried out to better understand the epidemiology, pathophysiology and intervention of tinnitus.

Hearing loss is most commonly associated with tinnitus. In 10-15% of people, tinnitus is reported with normal hearing sensitivity (Barnea, Attias, Gold & Shahar, 1990). Tinnitus is viewed as a compensatory response to cochlear damage, which may or may not elevate hearing thresholds. In cases with normal hearing, i.e. no peripheral damage, tinnitus might be perceived because of neuroplastic changes in the central auditory system, or it can manifest itself as a hidden hearing loss or subclinical pathologies missed out during routine evaluation (Henry, Roberts, Caspary Theodoroff & Salvi, (2014).; Kujawa & Liberman, 2009; Schaette & McAlpine, 2011). Tinnitus with normal hearing can be the first symptom of a disease that can be identified later in time after the hearing sensitivity deteriorates significantly. The pathophysiology of tinnitus with the normal hearing group is more obscure than the tinnitus with the hearing loss group. The heterogeneity in characteristics of tinnitus and its etiology makes understanding the underlying pathophysiology difficult and complicated. Various theories of tinnitus generation have been proposed. However, no one theory can fully explain the characteristics of tinnitus considering the wide range of involved

heterogeneity (audiological and non-audiological factors). In the last decade, there is a significant increase in the volume of research conducted on tinnitus with normal hearing. Using the PUBMED search engine with the keywords "tinnitus" and "normal hearing", a total of 117 published research articles are returned. Out of which, more than half of the articles are published after the year 2010.

2.1 Tinnitus and its definition

Tinnitus is basically defined as ringing in the ears when no external sound is present. Various definitions of tinnitus have been proposed. Shulman (1988) postulated that tinnitus is an abnormal percept and is not associated with any source of external stimulation. (McFadden & National Research Council (U.S.). Working Group 89. (1982) proposed that tinnitus is the conscious perception of sound originating in the head. Earlier definition described tinnitus as the sensation of sound originating in the head and neck area. Auditory hallucination was also described as tinnitus. These definitions kept on modifying to differentiate somato-sounds and other meaningful auditory hallucinations from the tinnitus with the ongoing research (Sreeraj, 2017). Jastreboff (1990) defined tinnitus as the perception of the sound resulting exclusively from activity in the nervous system in the absence of any corresponding activity in the cochlea (mechanical and electrical) and no external source of stimulation. This definition included meaningless subjective tinnitus and meaningful auditory hallucination under the same term (Jastreboff, 2011). However, the somato-sounds are excluded from this definition of tinnitus. Tinnitus is a phantom auditory perception (Jastreboff, 2011). The phantom auditory perception also includes the perception of understandable speech with voices in the ear. Auditory hallucinations are the hallmark of schizophrenia (Cloninger, Martin, Guze & Clayton, 1985). It is crucial to separate meaningless tinnitus and understandable speech perception because of the latter's

different treatment lines. The word tinnitus usually refers to subjective tinnitus only as it is more common. A clear definition is needed to bring uniformity in assessment and intervention strategies.

2.2 Prevalence of tinnitus

Tinnitus is reported commonly in all age groups. It is one of the most commonly reported symptoms in the otology clinic (Pajor, Ormezowska & Jozefowicz, 2013). According to Bhatt, Lin & Bhattacharya (2016), every 1 in 10 adults is reported to have tinnitus in the United States (US). Almost everyone has at least once momentarily experienced tinnitus might be after noise exposure (McFadden & National Research Council (U.S.). Working Group 89., 1982).

Different prevalence studies have yielded different prevalence across ages. These variations are attributed to the differences in definition & duration of the tinnitus and variations in methodology and geographical area (Henry, Dennis & Schechter, 2005). For people of all ages, the prevalence of tinnitus ranged from 4.4% to 15.1%. Research has unanimously concluded that tinnitus prevalence increases with age. For those aged above 50 years, the prevalence has been reported to be between 7.6% and 20.1% (Møller, 2007).

However, the prevalence has increased among younger age groups over the past decade, presumably because of increased exposure to damaging recreational noise (Degeest, Corthals, Vinck & Keppler, 2014). One of the most extensive studies for people aged over 14 years in New Zealand involved 69,976 participants. The overall prevalence of tinnitus was 6.0%. 6.5% among males compared to 5.5% among females. Tinnitus prevalence increased with age, peaking at 13.5% for older adults aged over 65 (Wu, Martel & Shore, 2016).

The prevalence of tinnitus in India is around 9.6% (Sreeraj et al., 2013). A one-year prevalence study of tinnitus in India for adults above 60 years of age on 2695 cases yielded a prevalence of tinnitus to be 16.81% (453 individuals). Of 453 individuals, 60.9% (276) were male, and 39.1% (177) were female. 97.5 % of individuals with tinnitus had hearing loss, and the remaining 2.5% had normal hearing sensitivity (Thirunavukkarasu & Geetha, 2013).

McCormack, Edmondson, Somerset, and Hall (2016), in a systematic review of 39 studies, reported the overall prevalence of tinnitus in between 5.1% - 42.7% covering 16 countries worldwide. Twelve studies out of 39 used the same definition of tinnitus and reported prevalence between 11.9% to 30.3%. A total of 26 studies analysed tinnitus prevalence by age and reported an increase in the prevalence of tinnitus with age. Authors also concluded that, in the general trend, males reported more tinnitus than women. They reported eight different definitions of tinnitus used by the 39 studies. This issue makes the direct comparison of the prevalence of tinnitus studies imprecise. There is a need for a uniform definition and methodology to be followed for such studies.

2.3 Tinnitus and duration

The episodes of tinnitus will have high variability in terms of its temporal aspects, psychoacoustical (pitch, loudness) and emotional responses. The duration of tinnitus can range from short (few seconds) to continuous. Consensus on the criteria to separate normal from pathologic tinnitus had not been achieved. Currently, most researchers use five minutes criteria proposed by the Medical Research Council-Institute of Hearing Research. However, this criteria is arbitrary and not based on any evidence (Jastreboff, 2011)

Tinnitus Screener, developed by Henry, Griest, Thielman, McMillan, Kaelin & Carlson (2016), identifies five different categories of tinnitus based on the temporal aspects and frequency of occurrence.

- Spontaneous tinnitus is a random occurrence of tinnitus and is lasting for few minutes or so. It can be accompanied by other otological symptoms such as ear fullness and hearing loss. All the symptoms resolve in 2-3 minutes. They do not require any clinical services.
- Temporary tinnitus is linked to noise exposure and tinnitus induced by medication. Anything which leads to a temporary shift in threshold (TTS) will lead to temporary tinnitus (Cunningham & Tucci, 2017). Temporary tinnitus can last for one or two days (Henry & Manning, 2019). They require education about the hearing conservation program.
- Occasional tinnitus is experienced irregularly. The frequency of occurrence is less than weekly. It lasts for more than five minutes. Occasional tinnitus with otologic complaints warrants a clinical intervention (Henry & Manning, 2019).
- Intermittent tinnitus is tinnitus that occurs at least twice a week. Tinnitus lasts at least five minutes. It can be either an acute or chronic condition (Henry, Griest, Thielman, McMillan, Kaelin & Carlson, 2016).
- Constant tinnitus is the perception of continuous tinnitus. It can also be acute or chronic (Henry & Manning, 2019). Both continuous and intermittent tinnitus need clinical intervention.

Temporary tinnitus is a prevalent symptom; permanent tinnitus is in about 10-15% of adults. Acute tinnitus usually resolves on its own. Temporary and occasional tinnitus patient needs tinnitus counselling and education about hearing conservation.

Spontaneous tinnitus is entirely normal and does not warrant any clinical procedure (Henry & Manning, 2019).

2.4 Tinnitus and characteristics

It is generally classified into two categories objective (somato-sound) and subjective tinnitus (Moller, 2007). Objective tinnitus is the perception of sound generated in the body reaching the ear through the conduction in the body tissue. The sound conducted through body tissue is generated by vascular flow or myoclonus spasms (*Tinnitus - Ear, Nose, and Throat Disorders - MSD Manual Professional Edition*, 2021). Objective tinnitus can be heard by the examiner outside too or sometimes by using a stethoscope (Møller, 2007). At the same time, subjective tinnitus is the perception of sound without any external sound reaching the ear. Subjective tinnitus is believed to be a pure electrochemical or neurophysiological process (Hertzano, Teplitzky & Eisenman, 2016). It is the sensation of phantom sound. On the contrary, objective tinnitus can be traced down to acoustic generators (Jastreboff, 2011). Objective tinnitus is a rare condition.

According to the American Tinnitus Association, 99% of tinnitus reported is subjective tinnitus. Although tinnitus is defined as the ringing in the ear, tinnitus can take the form of any non-meaningful sound. Tinnitus is reported in many forms ranging from hissing, buzzing, whistling, roaring, clicking, tonal, fluorescent light, running engine, humming, static or noise (Baguley, McFerran & Hall, 2013; Jastreboff, 2011). Perception of sound can be continuous or intermittent. It can be pulsatile (synchronous/nonsynchronous to heartbeat) or non-pulsatile. Some people will experience multiple sounds, and the characteristics of tinnitus keep changing (Cima et al., 2019). Subjective tinnitus will be different within and across individuals. Tinnitus

can range from a very low-intensity sound to sound loud enough to interfere with the perception of speech and other external sounds.

Tinnitus can be acute (<3 months), sub-acute (3-6 months) and chronic (>6 months). However, the chronological boundary between chronic and acute tinnitus is not clear. The range varies from 3-12 months since the onset of tinnitus (Haider, Bojić, Ribeiro, Paço, Hall & Szczepek, 2018). Chronic tinnitus is often a debilitating condition (Cima et al., 2019). It deteriorates an individual's Quality of Life (QOL). Tinnitus is similar to central neuropathic pain (Møller, 2007).

Most tinnitus cases are often not recognized as medical or auditory issues but are simply accepted as typical occurrences or mild irritants. On the other hand, tinnitus can be irritating for some people. For them, it might feel like a systemic disease. It can be severe enough to cause an otherwise healthy person to become ill. Someone who was formerly well-adjusted becoming unable to work or socialize (McFadden & National Research Council (U.S.). Working Group 89., 1982). Tinnitus is an insidious disease. It is annoying to some people and irrelevant and non-bothersome for others. The mechanism behind the response to tinnitus is still not clear.

For 80% of all the people who experience tinnitus, it is non-bothersome. For them, tinnitus is a benign symptom (Henry & Manning, 2019). Tinnitus is just like any other environmental sound with no reaction attached to it. On the contrary, for the other 20% of individuals, tinnitus is associated with a negative reaction. People with bothersome tinnitus experience something distressing and unpleasant for the most (or all) of their waking hours. Negative reactions to tinnitus are the impact of tinnitus in daily life. This included emotional distress, attention and concentration difficulties, depression, sleep disturbance, and other factors involving connections with the nonauditory area (Hippocampus and Amygdala) (Henry, Dennis & Schechter, 2005).

For understanding the annoyance associated with tinnitus in few individuals and non-bothersome in many. There is a need to understand the critical distinction between "perception of tinnitus." and "reaction to tinnitus." Perception of tinnitus refers to the mere sensation of sound without an external source, while the reaction to tinnitus refers to the distress and suffering associated with tinnitus (Henry & Manning, 2019). Along with such adverse effects, tinnitus has a functional effect, limiting the Activities of Daily Life. Sleep disturbance is the most common, poor concentration and anxiety (Erlandsson & Hallberg, 2000; Henry, Dennis, et al., 2005). The auditory system provides a mechanism for the generation of tinnitus, leading to "perception of tinnitus". On the other hand, "reaction to tinnitus" is the perception of tinnitus interacting with the nonauditory area. The auditory system provides a source for perception. Later, through inappropriately created functional connections, activates the limbic system and autonomic nervous system, resulting in distress and annoyance associated with tinnitus (Jastreboff, 2011). Recent research in rats (using fMRI) and humans (using intracranial recordings) suggests that emotional/cognitive relays in the brain, such as the temporal, sensorimotor, parietal, and limbic cortex, are involved in the pathophysiology of tinnitus (Frank, Schecklmann, Landgrebe, Burger, Kreuzer, Poepl & Langguth, 2012; Haider, Bojić, Ribeiro, Paço, Hall & Szczepek, 2018; Vanneste & De Ridder, 2011). Chronic debilitating tinnitus is likely to be a function of various complex network connections in CANS and nonauditory areas (Henry, Roberts, Caspary Theodoroff & Salvi, 2014). Although with current intervention, it is not possible to cure tinnitus (remove tinnitus percept) but an individual's reactions to tinnitus are modifiable.

2.5 Etiology of tinnitus

Tinnitus is a commonly occurring symptom. Tinnitus has many causes, and the origin of tinnitus in many individuals is still unknown (Kleinjung & De Ridder, 2011).

It is rarely known what the cause of tinnitus in a particular individual is (Møller, 2007). Tinnitus results from a gradual process (except in sudden hearing loss cases) leading to a decline in cochlear and neural functioning. Often, the process behind the perception of tinnitus starts without any external or internal events that can be identified (Møller, 2007).

Tinnitus is known to have trigger factors. Tinnitus is generally considered to be generated because of the loss of cochlear input to central structures. Sensorineural hearing loss (SNHL) is the most commonly associated with tinnitus (Eggermont, 2007). The presence of chronic progressive hearing loss is not sufficient enough to produce symptomatic tinnitus (Han, Lee, Kim, Lim & Shin, 2009). Small temporary changes in OHC following noise exposure can trigger tinnitus (Jastreboff, 2011). To elicit tinnitus, two or more risk factors have to act synergistically. Various factors such as noise exposure, psychological stress and somatic factors have been reported to trigger tinnitus (Shore, Zhou & Koehler, 2007). According to Jastreboff (2011), about 75% of new cases are related to emotional stress as the trigger factor.

However, about 40% of patients cannot identify any cause associated with tinnitus onset (Han, Lee, Kim, Lim & Shin, 2009). Tinnitus is not a disease itself but a symptom of various underlying disorders. The presence of different forms of tinnitus and its association with various other conditions make identifying the etiology of tinnitus difficult. Other than otological problems, cardiovascular, psychological, neurological, musculoskeletal, and nutritional issues have all been linked to tinnitus (Deklerck, Debacker, Keppler & Dhooge, 2020). "No one model fits all" for the pathophysiology of tinnitus led to uncertainty in the etiology of tinnitus, but various risk factors have been identified in the literature.

Based on epidemiological and clinical studies, tinnitus is known to be associated with various conditions. These conditions can be categorised as (Baguley, McFerran & Hall, 2013):

- **Otological:** Tinnitus is found to be associated with pathologies affecting all the parts of the human auditory system external ear (impacted cerumen), the middle ear (Otitis media, otosclerosis,) cochlear (NIHL, presbycusis, labyrinthitis, Meniere's disease, sudden hearing loss, acoustic trauma), neural (Vestibular schwannoma, ANSD).
- **Neurological:** Meningitis, encephalitis, migraine, epilepsy, multiple sclerosis
- **Traumatic:** Head or neck injury, whiplash injuries, RTA leading to unconsciousness
- **Orofacial:** Temporomandibular joint disorder (TMJ) (Objective tinnitus)
- **Cardiovascular:** Hypertension
- **Rheumatoid Arthritis**
- **Immune-mediated:** systemic sclerosis, Systemic lupus erythematosus
- **Endocrine and metabolic:** Diabetes mellitus, hypothyroidism, hormonal changes during pregnancy
- **Psychological:** Anxiety, depression, emotional trauma
- **Ototoxic medications**

. Several studies imply that noise trauma is the most common cause of tinnitus (18%), followed by head and neck trauma (8%), and ear infections and diseases (8%), with medicines accounting for only 2% of reported cases of tinnitus. (Henry, Dennis & Schechter, 2005). Hearing loss has been thought to be the most prevalent cause of tinnitus for many years, but population-based research suggests that excessive noise

exposure is the second most common cause of tinnitus. (Han, Lee, Kim, Lim & Shin, 2009).

2.6 Tinnitus and Associated risk Factors

Tinnitus is a symptom associated with multifactorial origin presenting with a myriad of symptoms. Often tinnitus does not occur in isolation, it happens in association with several factors. Tinnitus is most commonly associated with hearing loss. It can also be associated with many other conditions like noise exposure, ageing, ototoxicity. Depending on the etiology, pathophysiology, and reaction to tinnitus, it can lead to or be associated with otological problems, psychological problems, cardiovascular disease, systemic disease, & general health issues. Details of each associated condition are reviewed and given one by one.

2.6.1 Tinnitus and hearing sensitivity

Hearing loss is the only known cause of subjective tinnitus (ASHA, 2019). Some researchers believe that tinnitus cannot occur without hearing loss (American tinnitus Association, 2019). As a general rule of thumb, any disorder that causes hearing loss of any type (conductive/mixed/SNHL) can cause tinnitus, acute or chronic.

According to the "80/80 Rule," around 80% of persons with sensorineural hearing loss (SNHL) also have tinnitus, and approximately 80% of those with tinnitus also have SNHL (Mazevski, Beck & Paxton, 2017). There is a strong association between both, but the relationship is not straightforward. Almost every damage to the cochlea results in the loss of input to the Central Auditory Nervous System (CANS) (Henry, Roberts, Caspary Theodoroff & Salvi, 2014)). This loss is detected readily in the CANS. In a few days, the Dorsal Cochlear Nucleus (DCN) neurons increase the spontaneous firing rate and sound-induced neural firing (Brozoski Brozoski, Bauer & Caspary, 2002; Vogler, Robertson & Mulders, 2011).

In most people, tinnitus is a side-effect of the neuroplastic changes in the auditory system, which are compensatory. These compensatory changes are normal in nature because the system is always trying to restore homeostasis (Jastreboff, 2011). The compensatory changes are mediated by the help of a process called "homeostatic plasticity" (Haider, Bojić, Ribeiro, Paço, Hall & Szczeppek, 2018). Loss of input creates heterogeneity in input from adjacent frequency areas. This leads to an increase in firing rate, and perception of this increased neuronal activity is tinnitus. The matching of tinnitus pitch to the edge frequency in the audiogram is clinical evidence for the above model (Jastreboff, 2007).

Nevertheless, approximately 20% of people reporting tinnitus have hearing sensitivity within normal limits (Jastreboff, 2011). Xiong, Liu, Liu, Peng, Lin, and Sun (2019) reported that one-third of their outpatient tinnitus (primary complaint) patients had normal hearing sensitivity (<25 dBHL). Researchers have found the variable prevalence of tinnitus in normal hearing. To this day, tinnitus in persons with hearing sensitivity within normal limits is a challenge to model that relies on cochlear input loss (Schaette & McAlpine, 2011). Jastreboff (2011) attributed the perception of tinnitus with normal hearing sensitivity to the changes too small to be detectable in the standard audiogram. These small localized changes can result in an imbalance in input between adjacent frequencies, leading to the heterogeneity of inputs. Thereby inducing compensatory changes in the auditory system. The presence of tinnitus in persons with normal conventional audiometric threshold could be explained by generalized damage to up to 30% of the outer hair cells across the spiral of the cochlea, with no impairment to the hearing threshold at frequencies between 250 Hz and 8 kHz (Valente, Carvalho, Mezzalira, Stoler & Paschoal, 2012).

Kujawa and Liberman (2009) proposed that normal audiometric thresholds do not necessarily indicate completely normal function. They found that mice exposed to noise leading to mild acoustic trauma reveal Temporary Threshold Shift (TTS) but permanent deafferentation of 50-60% of high-frequency region nerve fibres. They also suggested that deafferentation is localized mainly to high threshold auditory nerve fibres. Hence, a sufficient amount of low threshold auditory nerve fibres remains intact and respond to sound. They defined this as Hidden hearing loss (HHL). Deafferentation, also known as cochlear synaptopathy, could lead to a compensatory response in the Central Auditory Nervous System. Based on the computational model of generation of tinnitus, Schaette and McAlpine (2011) hypothesized that the deafferentation of a substantial fraction of auditory nerve fibres could trigger neural correlate of tinnitus. They studied thirty-three females with hearing sensitivity within normal limits (125-8 kHz). Out of 33, fifteen participants had tinnitus, and the remaining eighteen did not report tinnitus. Auditory brainstem response (ABR) was recorded at 90 dB SPL and 100 dB SPL, respectively. They compared the wave I and wave V amplitude between the groups. Results revealed a significant difference in wave I amplitude between both groups. The Tinnitus group had lesser amplitude for wave I (generated from the primary auditory nerve). This reduced amplitude of wave I indicate the loss of a substantial number of nerve fibres. In contrast to wave I, wave V showed no significant difference between the two groups. This suggests that homeostatic changes in CANS leads to normalisation of wave V amplitude by increased central gain in response to loss of input. Thus, author concluded that these results provide the direct physiological evidence of Hidden Hearing Loss (HHL). HHL can manifest itself as presence of tinnitus, hearing difficulties in noise, feeling of reduced hearing sensitivity.

Cochlear pathology is not always expressed in the audiogram but may be detected by more sensitive measures (Henry, Roberts, Caspary Theodoroff & Salvi, 2014)). Shim et al. (2009) did a study on 18 tinnitus subjects with thresholds less than < 25 dB in a conventional audiogram (250- 8kHz). They compared it with five age-matched and gender-matched controls (no tinnitus and normal hearing) for each subject. They did Extended High-Frequency Audiometry (EHFA) at 10,12, 14 and 16 kHz. Results showed significantly poorer hearing thresholds at more than one of the four extended high frequencies compared to the control group without tinnitus. Out of eighteen tinnitus subjects, twelve have higher hearing thresholds at Ultra High Frequency (UHF).

Similarly, in another study, Omidvar, Jafari, Mahmoudian, Khabazkhoob, Ahadi, and Yazdani (2016) reported differences in the EHFA and TEOAE in individuals with normal hearing sensitivity with tinnitus and without tinnitus. They administered EHFA and TEOAE in eighteen tinnitus subjects and twenty- two control subjects. Considering TEOAE SNR and reproducibility, 72.2% of tinnitus and 18.2% of control ears had abnormal TEAOE. TEAOE abnormalities in 4 & 5 kHz region. There was a negative correlation between UHF thresholds and TEAOE SNR in the 2-5 kHz region. This suggested that in persons with tinnitus, there is subclinical damage of the cochlea.

Xiong, Liu, Liu, Peng, Lin, and Sun (2019) proposed that conventional audiograms take thresholds at only octaves and mid-octaves (if required). There are high chances that it can miss lesions between the tested frequencies. To investigate the hypothesis, they administered fine-frequency resolution (1/24 octaves) audiometry on hundred and six (106) subjects with normal hearing with tinnitus. DPOAE was also administered to check OHC integrity. Results revealed that 52 out of 106 individuals

(49%) had notched audiograms. Notches were coinciding with the tinnitus frequency. The frequency of these notches ranged from 144 to 8 kHz. Most of them had notches above 4 kHz. DPOAEs revealed that tinnitus patients had considerably lower OAE amplitude, implying that OHC dysfunction may factor in their notched hearing loss. However, DPOAE amplitudes were typical in thirteen out of thirty-one subjects, with a notched audiogram implying normal OHC functioning. This suggested notched audiogram is because of dysfunction of Inner Hair Cells (IHC) and/or afferent synapses. Normal audiometric function per se is unlikely to detect inner hair cell loss or auditory nerve damage (Henry, Roberts, Caspary Theodoroff & Salvi, 2014; Weisz, Hartmann, Dohrmann, Schlee & Norena, 2006).

Overall, it is now relatively well established that most of the nuclei in the auditory pathway can be affected during tinnitus. Perception of tinnitus depends on the role of auditory cortices (Eggermont, 2007). In terms of its origin, central tinnitus is defined as tinnitus originating in the CANS or any activity due to peripheral problems exaggerated by the auditory nervous system (Sbitz, 1981). The finding that tinnitus persists even after the bilateral sectioning of the auditory nerve strengthens the central origin theory (Henry, Roberts, Caspary Theodoroff & Salvi, 2014). The central origin of tinnitus is believed to be led by a loss of lateral inhibition. This reduction in inhibition is due to hyperresponsive CANS due to ageing (Gerken, 1996). The central origin theory of tinnitus can explain tinnitus with normal hearing sensitivity.

Apart from the "central origin" theory of tinnitus, it is believed that dysfunction of the efferent auditory system has a role in the perception of tinnitus. Riga, Papadas, Werner & Dalchow (2007) proposed that efferent auditory system dysfunction leads to tinnitus. They did a study on eighteen normal hearing individuals with acute (<3 months) tinnitus (bilateral in three and unilateral in the remaining fifteen). They

compared it with normal hearing individuals with no tinnitus and tinnitus ear with the non-tinnitus ear in individuals with unilateral tinnitus. They found that the application of contralateral noise enhances the activity of OHC or have a little suppression effect compared to the control group. Comparing the tinnitus ear vs non-tinnitus ear, authors found no significant difference in efferent auditory system functionality. Suggesting bilateral involvement of efferent auditory system in individuals with unilateral tinnitus. The pathophysiology of tinnitus with normal hearing is still unclear and is a matter of intense and ongoing research worldwide.

2.6.2 Tinnitus and noise exposure (Occupational & Recreational)

The role of continuous occupational noise exposure and acoustic trauma leading to hearing loss and tinnitus is well documented. After hearing loss, noise exposure is the second most commonly associated risk factor with tinnitus (Pavaci et al., 2019). About 20% of cases of tinnitus are linked to NIHL. Recreational- noise exposure is a concern of increasing occurrence. The potential harmful effects of recreational noise exposure can lead to tinnitus. The level of a concert or pop-music festival is reported to be around 95 dBA, with a range of 73-109 dBA (Eggermont, 2012). The increased use of personal listening devices led to an increased risk of cochlear damage, especially when used daily for an extended period of time. These devices can produce an output of 91-121 dBA (Eggermont, 2012). Consequently, noise exposure, both occupational and recreational, can lead to the development of tinnitus.

Occupational noise exposure was linked to a higher risk of frequent tinnitus in people with hearing loss. In comparison, leisure-time noise exposure was linked to a higher risk of frequent tinnitus in people without hearing loss (Eggermont, 2012). There is an increased risk of recreational noise exposure in the present day.

Rosanowski, Eysholdt. and Hoppe (2006) used transient-evoked otoacoustic emissions (TEOAEs) to see if young adults who attend discos would develop OHC damage. Eighty-eight young adults (47 women and 41 men, with an average age of around 23 years) were studied. Tinnitus was not a permanent problem for any of the participants. Transient tinnitus was detected by 16% after every discotheque visit and 58% after nearly every visit. After every visit to a disco, 8% experienced transitory hearing loss, and 37% experienced it after almost every visit. After visiting a disco, 3% had tinnitus every morning, and 4% reported it nearly every morning. TEOAE levels and repeatability dropped dramatically with more disco visits, indicating OHC damage without demonstrable pure-tone hearing loss. Noise exposure that produces only transitory threshold alterations in young mice has recently been demonstrated to cause delayed damage in spiral ganglion cells that manifests in maturity (Kujawa & Liberman (2009).

Boger, Sampaio, and Oliveira (2016) studied the hearing and tinnitus in normal-hearing workers exposed to occupational noise. They studied 150 subjects with normal hearing and a history of noise exposure above 85 dBA. A high prevalence of failure in DPOAE (40%) and tinnitus (66.6%) in subjects was observed. The greater the frequency of the sound, both in terms of amplitude and signal-to-noise ratio, the worse the outcomes. Despite audiometry being within normal ranges, the findings suggest that subjects suffer from the impacts of exposure and establish a link between otoacoustic emissions failure and tinnitus in this population.

2.6.3 Tinnitus and Ageing

Prevalence studies show that tinnitus is twice as common in the elderly than in young individuals. Tinnitus prevalence rises steadily until around the age of 70, after which it either remains constant or drops somewhat with age. Various characteristics

of the elderly can explain this rise in the incidence of tinnitus among the elderly: The high prevalence of SNHL in this group, as well as the presence of diseases (like vascular disease, middle-ear disease, diabetes, hypertension, autoimmune disorders and degenerative neural disorders) together with a rise in the usage of pharmaceuticals, and eventually life changes (retirement, loss of function, loss of identity, spouse or friends, or a reduction in social engagement) may result in mood, depression and anxiety (Rosanowski, Eysholdt. & Hoppe (2006).

McCormack, Edmondson, Somerset, and Hall (2016), in a systematic review, reported that 26 (66.7%) studies out of 39 showed tinnitus prevalence often demonstrate that as people get older, they have more tinnitus. For the age range 40–50 years, the prevalence was from 11.2% to 25.0%. For 50–60 years, the prevalence ranged from 9.5% to 29.8%. For 60–70 years, the prevalence ranged from 13.3% to 33.5%. In the age range 70–80 years, the prevalence ranged from 15.0% to 31.7%. However, some studies show that the prevalence of tinnitus peaks around 70 and then begins to diminish as people get older. The prevalence of annoyance associated with tinnitus increased with age (Deklerck, Debacker, Keppler & Dhooge, 2020).

A study by Martines, Bentivegna, Piazza, Martines, Sciacca, and Martinciglio (2010) analyses the characteristics of tinnitus with normal hearing vs tinnitus with hearing loss. A total of 312 participants with tinnitus were divided into two groups normal hearing (<20 dB) G1 (115, 36.9%) and hearing loss G2 (197, 63.1%). It was found that tinnitus prevalence increased with increasing age. For G1, i.e. normal hearing, the prevalence of tinnitus increased statistically significantly from 21 (18.3%) in the age range 21-30 years to 28 (24.3%) in the age range 41-50 years. Although in age ranges 61-70 & >70 years, the prevalence of tinnitus increased, but the increase

was only in G2. There was a decline in people with tinnitus having normal hearing sensitivity because of presbycusis in old age.

2.6.4 Tinnitus and gender

Researchers have found that males are affected more than females. Compared to males in females up to age 75 years, the prevalence is less; above this age, the gender difference is eliminated (Møller, 2011).

In the review study by McCormack, Edmondson, Somerset, and Hall (2016), it was found that 20 out of 39 studies reported tinnitus by gender. Out of 20, 16 studies (80%) reported a higher prevalence of tinnitus for men than women. Those studies reporting severity by gender, on the other hand, do not show a similar pattern, with half finding a higher prevalence of tinnitus severity in males and the other half finding a higher prevalence of tinnitus severity in females, and one study showing the same rate of tinnitus severity for males and females.

In contrast to this, many studies have found no correlation between gender and prevalence of tinnitus and its severity. Few studies have also found a higher prevalence of tinnitus in females compared to males.

2.6.5 Tinnitus and ototoxicity

Tinnitus has been connected to a variety of medications. Ototoxicity is generally associated with bilateral tinnitus. Although practically any prescription can cause tinnitus. A side-effect of various oral medications salicylates, nonsteroidal anti-inflammatory drugs, aminoglycoside antibiotics, loop diuretics, and chemotherapy treatments can cause tinnitus. Tinnitus is a common short-term side effect of many prescription drugs, and tinnitus symptoms usually go away once the patient stops taking the medication (Makar, 2021). Certain drugs are known to cause permanent symptoms, such as Nonsteroidal Anti-Inflammatory Drugs (NSAIDs), certain antibiotics

(aminoglycosides), cancer medications (cisplatin, carboplatin), Water pills and diuretics, Quinine-based medications (American Tinnitus Association, 2019).

Few drugs are not ototoxic but are usually associated with tinnitus lidocaine, anticonvulsants, antidepressants, cannabinoids, antihypertensives, beta-adrenergic blocking agents, opioids (buprenorphine), caffeine, and antihistamines (Enrico & Goodey, 2011).

The first link of tinnitus is the use of aspirin and quinine. These medicines may cause frequent, tonal tinnitus in form, accompanied by a transient threshold shift, and reversible when the medication is stopped (Salvago, Ballacchino, Agrifoglio, Ferrara, Mucia & Sireci, 2012). Tinnitus is the most common and early symptom of salicylate usage, and it can occur even at plasma levels of less than 100 mg/L, which rarely causes hearing loss (Eggermont, 2012). Aminoglycoside ototoxicity is amplified by a previous acoustic assault that does not cause persistent threshold alterations. Furthermore, noise-induced cochlear damage is aggravated by exposure to sub-damaging levels of aminoglycosides.

2.6.6 Tinnitus and Hyperacusis

Reduced sound tolerance (hyperacusis) is a common symptom of tinnitus. Defined as an aversion to loud sounds, 40% of patients with tinnitus have some degree of hyperacusis, and up to 86% of patients with hyperacusis also have tinnitus (Baguley, McFerran & Hall, 2013). The prevalence of hyperacusis is around 9-15% of the population, but it is more common in persons with tinnitus (Herráiz & Diges, 2011). Jastreboff and Hazell (1993) defined hyperacusis as a "manifestation of increased central gain", leading to enhanced perception of peripheral signals. They also considered hyperacusis as a pretinnitus state.

While hyperacusis is defined as the strong reaction to sound within the auditory pathway (Jastreboff, 2007), behaviorally, it is manifested as a patient experiencing a strong discomfort to sound (low/medium/high intensity). Usually, hyperacusis is suspected when the Uncomfortable Level (UCL) is at or below 90 dBHL (Herráiz & Diges, 2011). In tinnitus patients without hearing loss, hyperacusis is associated with higher amplitude of distortion product otoacoustic emissions (DPOAEs) (Sztuka, Pospiech, Gawron & Dudek, 2010).

Some neurotransmitters (serotonin, GABA) may have a role in this problem, as they are also involved in other hyperacusis-related diseases (migraine, depression) (Herráiz & Diges, 2011). According to some hypotheses, endorphins stimulate the excitatory action of glutamate, the principal auditory neurotransmitter, increasing its toxicity. Anxiety and stress cause endorphins to be released in the IHC–auditory nerve synapses. These chemicals promote excitement in the auditory periphery by potentiating the excitatory impact of glutamate. Marriage (1995) linked serotonin (5-hydroxytryptamine or 5HT) to migraine, depression, and posttraumatic stress syndrome, all of which are conditions linked to DST and may alter auditory signals. 5HT plays a crucial part in central auditory processing (CAP) and can be reduced as people age.

In a study on 250 patients with Decreased Sound tolerance (DST), Herráiz, Plaza & Toledano (2003) evaluated hyperacusis and tinnitus. The interference of DST and tinnitus on quality of life was assessed using direct questions and specific questionnaires. For 54 % of the participants, the answer to the question "do you feel more uncomfortable with environmental sounds than the majority of people?" was affirmative. Because of DST, 52 individuals had to discontinue one or more activities from a list of eleven (shopping, driving, child care, going to church, and so on).

Loudness Discomfort Levels (LDL) < 90 dBHL (criterion of hyperacusis) was found in 63% of the tinnitus clinic sample. Sixty-one % of the participants were women, with an average age of 51 years. 65% of the participants said they were anxious or stressed, and 15% said they had phobias like heights, restricted places, or insects. Sleep issues were also highly common (51%), and tinnitus was the primary cause of sleep loss in two-thirds of the patients. 83 % of the subjects had a hearing loss of more than 25 dBHL at any frequency.

2.6.7 Tinnitus and Psychiatric factors

According to ASHA (2019), excessive stress can cause tinnitus. Tinnitus is frequently associated with psychiatric comorbidity, particularly in severe cases. Depression, anxiety, somatoform disorders, psychosis, personality disorders, and body-concept disorders are only a few of the co-morbid psychiatric problems that have been observed in people with severe tinnitus. (Landgrebe & Langguth, 2011). Individuals with low and high distress in tinnitus do not differ in terms of its psychoacoustical (pitch, loudness) characters, but they differ in the presence of psychiatric comorbidity. Henry and Wilson (1995) reported that patients with higher scores on the tinnitus questionnaire suffer from psychiatric disorders than patients with low scores.

. The relationship between tinnitus and psychiatric symptoms is complex. The difficulty lies in determining whether tinnitus has caused reactive psychiatric comorbidity in an individual patient, or if a pre-existing but compensated psychiatric disorder shows up due to the tinnitus, or if well-managed tinnitus reappears due to the onset of a psychiatric (Landgrebe & Langguth, 2011). The involvement of limbic brain areas in the pathophysiology of tinnitus may explain the co-occurrence of tinnitus and depression. Tinnitus is linked to neuroendocrine changes, which are common in those who suffer from depression (Langguth & Landgrebe, 2011).

Anxiety is one of the most fundamental physiological emotions in humans. It is a biosocial signal that helps create normal interpersonal relationships and a risk-aware interaction with the environment. Anxiety manifests itself on a variety of levels, including emotional, cognitive (e.g. subjective beliefs about danger), motor (e.g. behavioural attitudes like fight, fright, or flight), and autonomic (e.g. physical reactions like tachycardia, stress hormone release). Tinnitus patients frequently experience anxiety. Co-morbid anxiety is linked to increased tinnitus severity and suffering, as well as an overall decline in quality of life. Tinnitus and anxiety disorders share similar brain locations in their pathophysiology, implying a close link between the two conditions (Langguth & Landgrebe, 2011).

Cortisol levels were examined by Hébert and Lupien (2009) in persons with high stress associated with tinnitus, low stress with tinnitus and controls. Chronic cortisol levels were higher in the high tinnitus-related distress group than in the low tinnitus-related distress and no tinnitus-related distress groups. In addition, they showed greater intolerance to external sounds than the control groups (hyperacusis). This shows a relationship between tinnitus sufferers' intolerance of both internal (tinnitus) and external sounds, which is consistent with the clinical finding that severe tinnitus is linked to high stress levels.

2.6.8 Tinnitus and sleep

Researchers have described disturbed sleep as one of the major components of tinnitus complaints preceded by hearing difficulties and emotional difficulties. The prevalence of sleep difficulties in tinnitus patients has been found to vary between 25 to 77% (Alster, Shemesh, Ornan & Attias, 1993).

Insomnia is more common in people who have recently developed tinnitus. Only 26% of people with tinnitus for more than 11 years reported sleeping problems,

compared to 45% of people with tinnitus for less than a year. There appear to be two types of insomnia in people with tinnitus: acute and chronic (Crönlein, Geisler & Hajak, 2011).

Restorative sleep is a basic health state, and one of the diagnostic criteria for insomnia is reduced daytime functioning (ICSD-2, 2005). Insomnia has been linked to various physical and mental health problems in a growing number of studies (Katz & McHorney, 1998). As a result, insomnia is a big health issue in and of itself, and disturbed sleep in tinnitus sufferers is a severe medical issue.

2.6.9 Tinnitus and non-otological conditions and other factors

Tinnitus is a prevalent symptom, and it is known to occur in a wide variety of disorders. Along with otological factors, tinnitus has been associated with many non-otological conditions also. Various researchers have found an association between tinnitus and non-otological conditions. Cardiovascular, psychological, neurological, musculoskeletal, and nutritional issues have all been linked to tinnitus (Deklerck, Debacker, Keppler & Dhooge, 2020). Metabolic disorders, hypothyroidism, anaemia, autoimmune disorders, Lyme disease, fibromyalgia, blood vessel disorders, high blood pressure, and atherosclerosis; traumatic brain injury caused by concussive shock can damage the brain's auditory processing areas, can result in tinnitus symptoms (Makar, 2021). ASHA (2019) reported that tinnitus could be linked to headaches, depression, diabetes. Shargorodsky, Curhan & Farwell (2010) reported a significant association between tinnitus and diabetes, hypertension and smoking.

Mezzalana Maudonnet, Pereira & Ninno, in 2004, studied 195 patients and divided them into two groups. G1 consisted of 64 patients with only tinnitus, and G2 consisted of 131 patients reporting tinnitus with either one or many of the hearing loss, dizziness, aural fullness. They studied the associated conditions and did a

comprehensive evaluation using an audiovestibular test battery. For the subjects in G1 with only tinnitus as a symptom, various conditions were reported. Noise exposure (12 participants), migraine (6), hypertension (14), diabetes (2), hyperlipidemia (6), pain at the nape of the neck (7), cardiopathy (2), TMJ dysfunction (4), facial paralysis (1), thyroid disease (3), allergic rhinitis (6), head injury (1), familial hearing loss (2) were reported. Along with these, few participants in G1 reported thyroid cancer, rheumatoid arthritis, osteoporosis, ocular herpes. Similar conditions were reported in G2, with hearing loss present. The audiovestibular test battery led to a probable etiological diagnosis in 48 (75%) participants and inconclusive in 16 (25%). Vascular disorders (26.5%), acoustic trauma (12%), and metabolic disorders (11%) were the most common causes of tinnitus in G1 patients; vascular disorders (20.7%), cervical disorders (11.5%), and metabolic disorders (10.7%) were the most common causes of tinnitus in G2.

Deklerck, Debacker, Kepler & Dhooge in 2020, did a systematic review of fifty-five studies for identifying non-otological risk factors. Various risk factors were identified, including cardiovascular, neurological, psychological, musculoskeletal and dietary factors. The general demographic risk factors were considered in 34 studies. Age and tinnitus prevalence showed a positive correlation in 18/29 studies. In contrast to other studies, gender results were ambiguous; 6/23 showed increased prevalence in females, 3/23 showed increased prevalence in males & 17/23 showed no gender effect. The impact of unemployment (4 studies), economic status (5 studies), bilateral handedness (1 study), family history of tinnitus (2 studies) all showed a positive correlation.

Cardiovascular risk factors were reported in 28 studies. Hypertension (20 studies), dyslipidemia (13 studies), ischemic heart disease (11 studies) transient

ischemic attack (8 studies) all showed a variable relationship with tinnitus. Psychological risk factors were reported in 25 studies. Depression showed the strongest correlation in 13/17 studies, anxiety in 4/8 studies and stress in 3/6 studies reported a positive correlation. Neurological and musculoskeletal risk factors were reported in 20 studies. In 6/8, 6/7, and 3/3 manuscripts, headache, including migraine, head injury, and whiplash, had a substantial connection with tinnitus. In 7/8, 5/6, and 2/2 manuscripts, particular joint problems such as temporomandibular disorder (TMD), arthritis, and rheumatoid arthritis were related to tinnitus.

2.6.10 Tinnitus and vestibular complaints

Tinnitus is associated with various vestibular problems. Almost every case of vestibular schwannoma reports tinnitus. Tinnitus can be caused by tumours such as vestibular schwannoma (VS) and cerebellopontine angle tumours, which place pressure on the high-frequency ANFs on the outside of the auditory nerve, resulting in a partial conduction block that limits output to the brain. Furthermore, VS may alter cochlear blood flow, resulting in sensory hearing loss.(May, Ramachandran & Cacace, 2011) Tinnitus is one of the triad symptoms of Meniere's disease. In more than half of the patients, fluctuating cochlear symptoms like tinnitus, hearing loss, and/or fullness in the ear were evident before the initial vertigo attack (Ying & Arriaga, 2011). Tinnitus is often the initial sign of Ménière's disease, and it might appear months or years before the other symptoms appear (Tokumasu, Fujino, Naganuma, Hoshino & Arai, 1996).

Shulman, in 1991, has demonstrated in their investigations, using routine cochleovestibular testing, that patients with tinnitus have a higher incidence of peripheral vestibular impairment, even when there is no accompanying vertigo. It was also concluded that tinnitus might be indicative of secondary endolymphatic hydrops.

Seabra & Diamantino (1995) reported that many tinnitus patients who do not report any vestibular symptoms have an abnormality in vestibular tests. They evaluated forty-four patients with tinnitus with an audiovestibular test battery. The test battery included Case history, ENT examination, PTA, speech audiometry, impedance audiometry and Brainstem Evoked Auditory Response (BERA). Vestibular tests included Cranio-Carpo-Graphy (CCG) and Electronystagmography (ENG) (caloric test). Results indicated that only 18% of participants reported vestibular problems when asked. Normal hearing sensitivity was present in 58% of participants. Tinnitus was the only symptom in 40% of participants. The authors concluded that in spite of only 18% of participants reporting vestibular complaints, 66% of participants have abnormal vestibular tests results. Of this, roughly half had indications of the peripheral lesion and the other half central lesions.

2.7 Assessment of Tinnitus

Tinnitus requires a multidisciplinary assessment. Audiologists play a critical role in the assessment process, assisting in determining the kind of tinnitus, conducting behavioural and electrophysiological evaluations, offering guidelines to support the diagnosis of underlying pathology, and setting a reference point for therapy techniques (Sreeraj, 2017). The assessment aims to identify any treatable condition leading to tinnitus (otological & non-otological); identifying risk factors present concerning tinnitus; assessing the functioning & integrity of the cochlea and the auditory nerve; quantifying the tinnitus (psychoacoustical aspects); assessing tinnitus handicap, and identifying any psychological problem (Cima et al., 2019; Landgrebe et al., 2012; Seabra, 1999; Sreeraj, 2017).

Tunkel et al. (2014) published an evidence-based clinical practice guideline (CPG) for tinnitus. The focus of the guideline was on the persistent subjective

bothersome tinnitus (> 6 months). However, in the guideline's executive summary, the authors have mentioned that it can also be used for a shorter duration of tinnitus. They used the term "duration of eligibility" for persistent tinnitus with a duration of 3 months and more (Tunkel et al., 2014b).

Table 2.1

KAS and action to be taken as recommended by Tunkel et al. (2014).

KAS	Statement	Action
1	History and physical exam	At the initial evaluation of a patient suspected of primary tinnitus, clinicians should carry out a "targeted history and physical examination" to discover diseases that may relieve tinnitus if recognized and treated immediately.
2A	Prompt audiologic examination	In patients with tinnitus that is either unilateral, pulsatile or associated with hearing difficulties, clinicians should get "prompt & comprehensive audiologic tests" done.
2B	Routine audiologic evaluation	Clinicians may obtain a routine or comprehensive audiological evaluation irrespective of its laterality, duration or perceived hearing status reported by the patient.
3	Imaging studies	Clinicians should strongly avoid imaging studies unless the tinnitus is "unilateral, pulsatile, associated with some neurological abnormalities or asymmetrical hearing loss."
4	Bothersome tinnitus	Clinicians should carefully identify and distinguish patients with bothersome tinnitus (affecting QOL) vs non-bothersome tinnitus.
5	Persistent tinnitus	To prioritize management and facilitate talks about natural history and follow-up care, clinicians should identify patients with bothersome tinnitus of recent onset from those with chronic symptoms (> 6 months).
6	Education and counselling	Patients with bothersome chronic tinnitus should be counselled about available management options.

The guideline provided evidence-based 13 key-action statements (KAS) for evaluation and management of tinnitus. Out of the 13 KAS first 6 are concerned with

the assessment, and the remaining 7 are concerned with tinnitus management in persons with no identifiable organic condition (except SNHL).

Fuller et al. (2017) reviewed the guidelines for assessing tinnitus in five different countries, including Germany, Sweden, Denmark, USA, and Netherlands. They summarised the assessment guidelines as:

- Conducting a comprehensive physical examination to rule out any potential underlying causes (neurological, ENT, identification of any cardiovascular disease) of tinnitus (recommended by three of the five countries; not indicated in Danish or Swedish).
- Carrying out a comprehensive audiological evaluation (all guidelines).
- Using a validated and accurate multi-item questionnaire such as the Tinnitus Questionnaire (TQ) (Goebel & Hiller, 1994), Tinnitus Handicap Inventory (THI) (Newman, Sandridge & Jacobson, 1998), Tinnitus Functional Index (TFI) (Meikle et al., 2012), or Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983), for determining the degree to which a patient's subjective tinnitus is unpleasant or disturbing (all guidelines).
- Consider referring patients to a psychologist or psychiatrist to examine if they appear to be experiencing distress or difficulty due to their tinnitus (indicated in four of the five countries, except in German guidelines).
- Variations existed in the use of imaging techniques (e.g. MRI) across all guidelines.

The authors concluded that the differences in the recommended assessment guidelines existed regarding the use of specific techniques (questionnaires, diagnostic tests and type of scanning or imaging techniques) rather than the general principles. The consensus was present on the initial need to exclude the physical cause of tinnitus,

conducting audiological evaluation, using relevant questionnaires to establish distress associated with tinnitus, and making appropriate referrals accordingly.

Schechter & Henry (2002) proposed a minimal test battery for evaluating persons with tinnitus. The test battery included:

- A comprehensive and targeted tinnitus history.
- ENT examination.
- Audiological evaluation and site-of-lesion testing.
- Tinnitus measurements including pitch matching, loudness matching, residual inhibition and minimum masking level.

There are various audiological tests available at the clinician's disposal to assess individuals having tinnitus with normal hearing sensitivity. These tests add value to differential diagnosis, identify pathophysiology and for counselling and selecting the appropriate management option (as required). These tests are described

2.7.1 Case history

In all areas of medicine, the case history is critical for accurate diagnosis; this is especially true for tinnitus, which is primarily a self-report phenomenon (Langguth et al., 2011). The following areas should be explored comprehensively:

- Primary demographic details (age, gender, family history) & occupational history (Langguth et al., 2011).
- The origins of tinnitus and its descriptive qualities (pulsatile/non-pulsatile; continuous or intermittent) (Langguth et al., 2011). The onset of tinnitus, whether it was sudden or gradual (Cima et al., 2019)
- The characteristics of tinnitus pitch, loudness, site of tinnitus (unilateral/bilateral/intracranial) and quality of the tinnitus (in own words) (Langguth et al., 2011).

- When was tinnitus first noticed; what are the main clinical factors (noise trauma, stress, acute sickness, and others) (Cima et al., 2019).
- Factors that can aggravate or alleviate tinnitus severity; (Langguth et al., 2011). (orofacial, cervical, or ocular motions, head postures, jaw movements, jaw muscle tension, and physical activity) (Cima et al., 2019).
- Tinnitus induced specific behavioural, social, interpersonal, and emotional implications (Langguth et al., 2011). Is tinnitus bothering or interfering with everyday life (sleep disturbances, task interruptions, scared emotions, cognitive-attentional issues, adverse reactions) (Cima et al., 2019).
- The level of tinnitus awareness is critical: can tinnitus be perceived only in silence or also in noise; Is tinnitus easily concealed or exacerbated by ordinary background noise (Cima et al., 2019).
- Associated otological complaints (reduced hearing sensitivity, speech in noise difficulty, ear fullness, vertigo or imbalance, hyperacusis, etc (Cima et al., 2019; Langguth et al., 2011)
- Medical history: orthopaedics, cervical, dental, and jaw surgery; internal medicine (thyroid, hypertension, anaemia); mental problems (psychological, psychiatric) (Cima et al., 2019).
- Long-term pharmaceutical usage; drug history/medications (Cima et al., 2019).
- Recent life events induced stress (Cima et al., 2019).

An "items list" for tinnitus case history questionnaires was developed during a consensus workshop on tinnitus assessment held in Regensburg in July 2006. Fourteen items on this list are essential (level A) and 21 highly desirable (level B) items. A case history questionnaire named "Tinnitus Sample Case History Questionnaire (TSCHQ)"

was developed based on this. TSCHQ is available in various languages (Langguth et al., 2007).

2.7.2 ENT examination

An otolaryngologist is the first point of contact for many persons who acquire tinnitus for the first time (Kleinjung, 2011b). The otologic examination is critical for identifying underlying causes that may be treatable with medical or surgical intervention (Kleinjung, 2011a). Tinnitus can be objective or subjective due to problems with the conducting apparatus of the ear.

Otoscopy is ideally performed for all cases of tinnitus. External ear examination can identify developmental defects that are significant for tinnitus diagnosis. Cerumen impaction can cause tinnitus (Sreeraj, 2017). Bony exostoses and tumours on the skin bordering the ear canal should be investigated (Kleinjung, 2011a).

When otologic investigations are inconclusive about diseases that may be causing tinnitus, radiological examinations may be indicated. The petrous section of the temporal bones can be utilized to detect and assess structural bony changes in the external ear and its surroundings, the middle ear, and the inner ear using high-resolution computed tomography (CT) (Branstetter & Weissman, 2006). MRI can be used for identifying intra- or extra-meatal tumours. The diagnosis of pulsatile tinnitus can be aided by Doppler examinations of vessels in the neck (Kleinjung, 2011a). The proper diagnosis is achieved using a combination of otological, radiological, and audiological data.

2.7.3 Pure tone Audiometry (PTA)

Pure-tone audiometry is recognized as the "gold standard" test for sequential testing of auditory function, with internationally accepted methods for determining hearing thresholds with accuracy (Coles, Lutman & Buffin, 2000). Ukaegbe,

Ezeanolue & Orji (2016) evaluated adults with self-reported normal hearing and chronic tinnitus had their audiometric hearing thresholds tested. Forty-three persons in the study reported continuous tinnitus but no history of hearing loss. Thirteen of them claimed to have bilateral tinnitus. As a result, they had a total of 56 ears with continuous tinnitus to analyse. The average length of tinnitus persistence was 17.3 months. Twenty experienced continuous tinnitus, whereas the other twenty-three had intermittent tinnitus. Eight of the participants had previously been exposed to loud noise. Fourteen of them admitted to taking medicines that could cause tinnitus. Seven participants were hypertensive, two reported having diabetes, and one reported having both hypertension and diabetes. They were all on medication. A total of 50 adults (100 ears) with normal hearing and no tinnitus were enrolled in the control group. Compared to the 100 control ears, the 56 ears with tinnitus exhibited a considerably higher mean Pure Tone Average (PTA). The mean PTA of the affected ear and the contralateral ear did not differ significantly in people with unilateral tinnitus. Also, the control group's PTA was much higher than the 30 contralateral (non-tinnitus) ears' PTA in persons with unilateral tinnitus. Individuals with tinnitus had a higher mean PTA than those without tinnitus, indicating that people with tinnitus are more likely to have a hearing impairment. The thresholds of pure-tone audiometry in the contralateral non-tinnitus ear in people with unilateral tinnitus are likely to be higher than in people who do not have tinnitus, indicating a similar pathology to the tinnitus ear.

2.7.4 Speech Audiometry & Loudness Discomfort Levels (LDL)

Speech recognition is one of the most critical components of human auditory function since it allows people to communicate effectively, which is essential for social integration. The relation between PTA and Speech recognition threshold is well established.

Hennig, Costa, Urnau, Becker & Schuster (2011) assessed and compared speech recognition in individuals with normal hearing sensitivity with and without tinnitus and hyperacusis. The experimental group consisted of 19 people with normal hearing sensitivity who had tinnitus and hyperacusis. In comparison, the control group consisted of 23 people with normal hearing sensitivity who had no audiological symptoms. The results showed that individuals in both groups performed similarly in speech recognition in silence, indicating that the ability to recognize speech in silence depends on tonal thresholds only and not on tinnitus.

In contrast, significant disparities in speech audiometry findings between tinnitus and non-tinnitus ears have been discovered. In both tinnitus and non-tinnitus ears, Speech Recognition Thresholds (SRT) and Speech Identification Scores (SIS) were compared. The results showed that in non-tinnitus ears, both measures were better, and this difference was statistically significant (Gudwani, Munjal, Panda & Verma, 2013). As a result, speech audiometry findings must be considered during the tinnitus evaluation process.

It is believed that 40% of those who suffer from tinnitus also suffer from hyperacusis. Overstimulation of the auditory system may cause discomfort in some patients (Ambrosetti & Del Bo, 2011). The auditory stimulation threshold that causes discomfort to the patient (loudness discomfort level – LDL) is used to study hyperacusis. A lower-than-normal level of discomfort characterizes hyperacusis. LDL for both pure-tone and speech-stimuli should be established (Ambrosetti & Del Bo, 2011).

2.7.5 Extended High-Frequency Audiometry (EHFA)

The effectiveness of traditional pure-tone audiometry in predicting cochlear damage is questionable. Hair cells that code conventional frequencies or frequencies

above 8000 Hz may be damaged beyond the detection range of conventional frequency audiometry. In addition, people with tinnitus and a normal audiogram were shown to have damage in their cochlear inner hair cells (Weisz et al., 2007). Individuals with tinnitus have higher hearing thresholds in pure-tone audiometry, especially in the extended high frequencies (König, Schaette, Kempster & Gross, 2006; Martines, Bentivegna, Martines, Sciacca & Martinciglio, 2010). In the high/ultra-high frequency range, tinnitus has been recorded in persons with normal hearing with tinnitus (Sreeraj, 2017).

Shim et al. (2009) compared hearing thresholds at ultra-high frequency areas were in people with normal hearing sensitivity and tinnitus symptoms with normal hearing and no tinnitus. Compared to control group participants, 12 of the 18 people who complained of tinnitus had significantly higher thresholds at more than one of the ultra-high frequencies examined. Results revealed that eight individuals experienced hearing problems at 10000 Hz, ten had hearing problems at 12000 Hz, eight had hearing problems at 14000 Hz, and four had hearing problems at 16000 Hz. As a result, the authors stress the importance of conducting extended high-frequency audiometry in tinnitus patients.

Sreeraj (2017) studied 32 individuals with normal hearing with tinnitus and compared EHFA thresholds with the control group (30 individuals with normal hearing and no tinnitus). The results revealed that the experimental group's thresholds in the extended high-frequency range were significantly poorer than the control group. The thresholds in the experimental group increased as a function of frequency despite no significant difference in the conventional audiogram.

2.7.6 Psychoacoustic measures of tinnitus

The psychoacoustical correlates of sound help a clinician to quantify subjective tinnitus. These measures include pitch matching, loudness matching, post-masking effect- the measure of residual inhibition. There is no relationship between pitch, loudness, and tinnitus severity (Jastreboff & Hazell, 2004).

The pitch most close to tinnitus has been found to range from 80 Hz to 16000 Hz (Henry & Meikle, 2000). They also reported that the degree of hearing loss inversely correlated with the pitch of the tinnitus. Hébert & Fournier (2017) studied the psychoacoustical measures of tinnitus in the normal hearing and hearing loss group. They reported the predominant pitch as 14.64 kHz in normal hearing and 8.5 kHz in the hearing loss group. The loudness in both the group did not show any significant difference.

Sreeraj (2017) reported the mean loudness of tinnitus in normal hearing to be 23.04 dBSL ranging from 5 dBSL to 55 dBSL and frequency range from 125 Hz to 12500 Hz. Duration varied from 4 to 48 months. Residual inhibition was complete in 1 individual, in 7 individuals partial and in 20 individuals, residual inhibition was absent. He also found no correlation between pitch, loudness, THI scores and residual inhibition in individuals with normal hearing with tinnitus.

2.7.7 Immittance Measures: Tympanometry and Acoustic reflex testing

Tinnitus can be caused by a variety of external and middle ear disorders. Overproduction of cerumen within the external auditory canal can significantly reduce sound energy reaching the tympanic membrane and/or limit membrane mobility, resulting in hearing loss and tinnitus. Tinnitus can be associated with infections, mechanical and neoplastic changes in the middle ear. Tympanometry is helpful in the diagnosis of tinnitus because it detects ears with abnormal Eustachian tube and/or

middle ear functioning, which can induce or exacerbate tinnitus (Fabijańska et al., 2012).

Acoustic reflex assessment has long been regarded as a valuable tool for assessing efferent auditory circuits. Hall & Haynes (2001) recommended tympanometry and acoustic reflex testing with caution of LDL in persons with tinnitus. Sreeraj (2017) reported no significant difference between ipsi and contra acoustic reflex levels in individuals with tinnitus and no tinnitus. The decay in the strength of the acoustic reflex response after sustained stimulation may be an indicator of auditory nerve disorders. However, the test's validity has been questioned (Ambrosetti & Del Bo, 2011).

2.7.8 Otoacoustic Emissions (OAE)

OHC are the common site associated with tinnitus. Spontaneous Otoacoustic Emissions (SOAE), Transient Evoked Otoacoustic Emissions (TEOAE), Distortion Product Otoacoustic Emissions (DPOAE) are well-studied with respect to tinnitus.

Thabet (2009) used TEOAEs and the threshold equalizing noise (TEN) test to see if there was any underlying cochlear damage (associated with OHCs and IHCs) in 20 people with unilateral tinnitus and normal hearing sensitivity. The contralateral ear served as the control ear. TEOAEs were aberrant in 85 percent of tinnitus ears than 20 percent of control ears, which was statistically significant. The tinnitus ear, compared to the control ear, showed a significant abnormality above 4-5 kHz in TEOAE. Only 15% of the ears with tinnitus had cochlear dead regions, according to the TEN test. This could be owing to the fact that IHCs are more resistant to injury than OHCs. This study found a higher prevalence of OAE abnormalities in people with tinnitus and normal hearing sensitivity in contrast to the TEN test.

In a study of 57 ears with normal hearing having tinnitus and 90 ears with normal hearing and no tinnitus. SOAE was found to be present in 34 ears (37.7%) in the control group and 24 ears (42.2%) of the clinical group, and the difference between the groups did not vary significantly. Out of the 57 tinnitus ear, TEOAE was present in 27 ears (47.3%) and absent in 30 ears (52.6%). A significant difference was found in mean TEOAE amplitude between the tinnitus and non-tinnitus groups, indicating a cochlear dysfunction. 88% of the clinical group had either absent, reduced or robust TEOAE. Also, there was no significant difference between the TEOAE amplitude in unilateral tinnitus vs bilateral tinnitus and between the right and left ear in the tinnitus group (Dhanya, 2010)

Similarly, mean DPOAE amplitude showed a significant difference at all frequencies between the tinnitus group and non-tinnitus group. In 93% of the cases, DPAOE was either absent, reduced or robust. There was no significant difference in the tinnitus group for DPOAE amplitude between unilateral and bilateral tinnitus and between the right and left ear. For individuals with TEOAE in the clinical group, the contralateral suppression of TEOAE was significantly reduced in at least one of the frequencies in 74% of the cases. This suggested efferent system dysfunction in individuals with normal hearing sensitivity and tinnitus.

Sreeraj (2017) recorded DPOAE fine structure with maximum available points per octave (19 to 51) in normal hearing with tinnitus and normal hearing with no tinnitus group. Ripple height was significantly higher in the tinnitus group, while ripple width was significantly lower in the tinnitus group. Because the tinnitus patients in this study exhibited normal hearing sensitivity. The fine structural variability could be interpreted as a sign of sub-clinical damage in the cochlea, particularly in the regions tuned to higher frequencies. When comparing those with tinnitus to those without, the

contralateral suppression of DPOAEs was greater in those with tinnitus. The hyper-responsiveness of the Medial Olivary Complex (MOC) system stimulated by noise stimulation is likely to cause this greater suppression in those with tinnitus.

2.7.9 Auditory Evoked Potentials (AEP)

Auditory Brainstem Response (ABR) can be used to evaluate people for various reasons, including its objectivity in evaluating the cochlea and auditory brainstem pathways. According to the research, the cochlea, auditory pathways, and the cerebral cortex are all implicated in tinnitus symptoms.

Schaette & McAlpine (2011) conducted a study on ABR parameters in tinnitus. The clinical group had 15 females with normal hearing and tinnitus. The control group consisted of 18 females (age-matched) with normal hearing and no tinnitus. The average amplitude of peak I, when compared to the control group, was much lower in the tinnitus group. This showed a lower number of sensitive auditory nerve fibres, or dyssynchrony in their discharge, or both. The tinnitus and non-tinnitus groups had similar peak V amplitudes, showing that homeostatic processes within central auditory structures change neuronal response to compensate for the diminished input from the auditory nerve. They concluded that deafferentation of a large number of auditory nerve fibres could cause a neurological correlate of tinnitus in the central auditory system.

Abnormal ABR findings in ears with tinnitus have been reported in the literature, including changes in the ABR waveform morphology indicating a central origin of tinnitus (Shulman & Sbitz, 1981), significant prolongation of peak I latency, decreased or increased I - V inter-peak latency, and decreased amplitudes of peaks I and III (Lemaire & Beutter, 1995).

Sreeraj (2017) compared ABR amplitude and latency parameters of peak I, III and V in tinnitus vs non-tinnitus group with normal hearing. Absolute latency, absolute

amplitude, and inter-peak latencies were all different between the two groups. Except for Peak I latency, no statistically significant variations were found.

Long-Latency Response (LLR) is characterized by a series of electrical changes in the central nervous system due to auditory sensory pathway stimulation. Tinnitus patients have aberrant LLR findings, according to the literature (Sreeraj, 2017). Sreeraj (2017), the LLR peaks P1, N1, P2, and N2 were studied in latency and amplitude parameters in normal hearing with tinnitus vs non-tinnitus group. Results revealed that in terms of latency and amplitude, the comparisons show a significant difference between the two groups in the P1 of LLR. Individuals with tinnitus had a shorter latency and a higher amplitude.

2.7.10 Tinnitus Questionnaires

Psychoacoustic or physical approaches are insufficient to depict people's reactions to their reported tinnitus experiences. Tinnitus questionnaires can assist identify those who are particularly troubled by their tinnitus (Noble, 2001). A self-assessment tinnitus questionnaire, which can indicate how the affected individual feels about the problem, might be an essential aspect of the audiological evaluation. These methods may also be used to identify patients, identifying those who require extensive rehabilitative management vs those who only require basic counselling. They are also employed in pre-and post-treatment analyses to assess the treatment's efficacy.

There is a multitude of questionnaires available to assess various elements of tinnitus. The qualitative tinnitus questionnaires are descriptive rather than score-based. This includes the initial intake interview (Henry, Jastreboff & Jastreboff, Schechter & Fausti, 2002), open-ended approaches for getting information about the patient's concerns (Tyler & Baker, 1983), and daily monitoring diaries. The score-based quantitative tinnitus questionnaires are also available. Quantitative tinnitus

questionnaires include the Subjective Tinnitus Severity Scale (Halford & Anderson, 1991), Tinnitus Handicap Inventory (Newman, Jacobson & Spitzer, 1996), and Tinnitus Handicap Questionnaire (Kuk, Tyler, Russel & Jordan, 1990).

THI is the most commonly used self-report questionnaire and is validated in many languages. The THI consists of 25 items divided into three subscales. The functional subscale (11 items) assesses an individual's limits in the areas of mental, social, occupational, and physical functioning. Anger, melancholy, frustration, and irritation are all assessed on the emotional subscale (9 questions). The catastrophic subscale (5 questions) indicates the most powerful tinnitus reactions, such as loss of control, desperation, inability to manage, inability to escape tinnitus, and the fear of having a serious condition. The tinnitus sufferer is asked to answer yes (4 points), sometimes (2 points), or no (2 points) to the questions (0 points). The degree of tinnitus is determined by a rating system that ranges from "slight" to "catastrophic." The THI has excellent reliability, internal consistency, and test-retest reliability (Sreeraj, 2017).

2.7.11 Vestibular Assessment

Any condition affecting the labyrinth has been known to cause a vestibular issue with cochlear issues (tinnitus, hearing loss). Connections between the central vestibular pathways and the auditory, visual, and somatosensory systems may also play a role in tinnitus processes (Herráiz, 2011). When a vestibular disorder is suspected in a patient, an extensive otoneurological examination is warranted. The most crucial information regarding the etiology and severity of the symptoms will come from the medical history. The three main systems examined are the vestibuloocular reflex, the vestibulo-spinal reflex, and the cranial pairs and cerebellum. Only specific types of tinnitus where the vestibular system is suspected to be implicated, such as in the case of vestibular schwannoma, can be diagnosed with otoneurological evaluation in patients with

tinnitus. If tinnitus is accompanied by vertigo or other types of dizziness, an otoneurologic examination may be necessary. The instrumental examination will objectify and measure some elements of the vestibular dysfunction, which is usually done in the chronic stages (Herráiz, 2011).

Chapter 3

METHODS

The study aimed to compare the clinical test battery used to assess the hearing status of individuals who reported to All India Institute of Speech and Hearing (AIISH) having tinnitus with hearing sensitivity within normal limits with the evidence-based assessment protocol from the available literature. The study's objectives included identifying the components of clinical assessment, identifying associated signs and symptoms, critically evaluating the clinical assessment protocol and comparing it with the protocol available to assess hearing status in the literature for individuals having tinnitus with normal hearing sensitivity. Another objective was to find the relationship between various signs and symptoms with test findings to arrive at a time-efficient suitable protocol instead of carrying out all the available audiological tests to assess such individuals. Based on the aims and objectives mentioned above, the following methodology was used to conduct the study.

3.1 Research design

The present study used a register-based research design to determine the clinical audiological tests administered for persons with normal hearing sensitivity having tinnitus.

3.2 Selection of participants

A total of 30 case files of clients who reported to AIISH from January 2019 to December 2019 and meeting the below-mentioned criteria were selected for the study. AIISH client databases were assessed, and case files of the participants were selected based on the following criteria:

3.2.1 Inclusion criteria:

The participants who met the below-mentioned criteria were considered for the study:

1. Individuals with ages between 15 -55 years having tinnitus.
2. Individuals diagnosed as bilateral normal hearing sensitivity or bilateral hearing sensitivity within normal limits (PTA \leq 15 dB HL).
3. Individuals who reported having tinnitus for at least three months either unilaterally or bilaterally.
4. Individuals who underwent ENT evaluation at AIISH.

3.2.2 Exclusion criteria:

The following participants were excluded from the study:

1. Individuals with middle ear disorder, indicated by tympanogram other than "A/A_s" type.
2. Individuals not having a good SRT-PTA correlation.
3. Individuals who reported to have acute tinnitus, i.e. tinnitus, since \leq 3 months.

3.3 Procedure:

The study was conducted in two phases.

- Phase-I: Retrospective analysis of case files.
- Phase-II: Extraction of evidence-based assessment protocol from literature.

3.3.1 PHASE I: Retrospective analysis of case files

In this phase, the case files of individuals with normal hearing reported to have tinnitus were selected, and the clinical test battery approach was analysed.

This phase included:

1. Selecting the case files.
2. Profiling the case history parameters to extract important demographic details, signs and symptoms associated with tinnitus and associated problems
3. Identifying the components of clinical test battery and findings of the various tests administered.

Selecting the case file. With permission from the concerned authority, the data from the AIISH Client Database Management Software (CDMS) for persons diagnosed as having "normal hearing sensitivity" or "hearing sensitivity within normal limits" with tinnitus were retrieved. The following settings were used in the search criteria:

Table 3.1

Search criteria used to extract the client file from AIISH CDMS:

Demographic details		Eligibility Criteria
Dates	From	01-01-2019
	To	31-12-2019
Age	Minimum	15 years
	Maximum	55 years
Gender		Both
Language		All

Table 3.2*Client's information criteria used to select eligible individuals*

Diagnostic Factor	Criteria Applied
Complaint history	a) R: Tinnitus; L: Tinnitus (bilateral (B/L) tinnitus) b) R: Tinnitus; L: Any other history (unilateral (U/L): R tinnitus) c) R: Any other history; L: Tinnitus (unilateral (U/L): L tinnitus)
Other complaints	If any
Degree of hearing loss	R: Normal; L: Normal
Cause	Any

Note: R: Right ear L: Left Ear

The above-mentioned filters settings combinations for complaint history were used for retrieving the case file from the AIISH CDMS for two different groups, one with bilateral tinnitus having normal hearing sensitivity and another with unilateral tinnitus (compromising of individuals with tinnitus either in R ear or L ear) having normal hearing sensitivity. The participants details were retrieved based on the mentioned filter settings (Table 3.1 & 3.2). The case files were analysed individually, and data were extracted from case files. Case files falling within the exclusion criteria were excluded.

Various diagnostic tests are generally applied as a part of clinical test battery on a case-to-case basis. Each case is evaluated with a minimum test battery, and few additional diagnostic tests are done as and when required. From each case file, the following information was looked into and tabulated based on the tests that have been administered: comprehensive case history, Pure tone audiometry (PTA), Speech

Audiometry, Uncomfortable level (UCL), Tympanometry, Acoustic reflex threshold testing (ART) (ipsilateral & contralateral reflexes), Reflex decay test (RDT), Otoacoustic emissions (OAEs) and Auditory brainstem response (ABR)tinnitus matching and residual inhibition and other tests which were included in the test battery used to arrive at a diagnosis. A total of 30 case files were selected based on the inclusion criteria. Three case files were not considered for analysis because they had tympanogram other than the "A/As" type though they had normal hearing with tinnitus. Thus, 27 case files were selected for analysis.

Analysing the case file. For all the 27 selected case files, a detailed case file analysis was done, which included profiling of:

- Age and gender of the individuals.
- The occupational history of the individuals.
- The primary and secondary otological complaints.
- The associated non-otological complaints.
- Medical history of the individuals.
- Subjective description of tinnitus, onset of tinnitus.
- Duration from which tinnitus is perceived.
- Components of the clinical test battery administered.
- Findings of the different audiological tests administered.
- Tinnitus handicap inventory (THI) scores (if available).

3.3.2 PHASE II: Extracting evidence-based Assessment Protocol from the literature

1. A literature review was carried out to identify different characteristics, associated conditions, etiology, and pathophysiology associated with the perception of tinnitus in individuals with normal hearing sensitivity.
2. The clinical utility of various audiological tests as a component of clinical test battery protocol was determined with reference to evidence-based literature. For this purpose, high-quality evidences were searched in the literature. The Clinical practice guidelines and systematic reviews concerning tinnitus evaluation protocol published in the literature were reviewed. The following articles were selected for the analysis purpose:
 - **Study 1:** "A multidisciplinary European guideline for tinnitus: diagnostics, assessment, and treatment." (Cima et al., 2019).
 - **Study 2:** "Different Teams, Same Conclusions? A Systematic Review of Existing Clinical Guidelines for the Assessment and Treatment of Tinnitus in Adults" (Fuller et al., 2017).
 - **Study 3:** "Siemens expert series: Evidence-based management of troublesome tinnitus—practical guidelines for the practicing professional." (Hall, 2013).
 - **Study 4:** "Clinical Practice Guideline: Tinnitus" (Tunkel et al., 2014) published by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)
 - **Study 5:** "Audiologic Guidelines for the Diagnosis and Management of Tinnitus Patients" (American Academy of Audiology position statement).

All the guidelines have provided different levels of recommendation for various diagnostic and treatment procedures for persons experiencing tinnitus regarding various

evidence reported in the literature. Based on “Oxford Centre for Evidence-Based Medicine: Levels of Evidence (OCEBM, 2009)”, studies 1, 2 and 4 are level 1a of evidence and study 3 and study 5 are level 5 of evidence.

3.4 Analysis

The data was collected from the retrospective case file analysis and was analysed using appropriate descriptive statistics tools. Descriptive analysis of various case history factors reported in the case files was done. Afterwards, a comparison was made between the clinically reported conditions/factors with the tinnitus associated factors available in the literature for individuals having tinnitus with normal hearing. After analysing the clinical test battery protocol, a critical evaluation of the audiological test administered and the evidence-based test battery recommended in the literature for persons with normal hearing sensitivity and tinnitus was carried out and discussed. Shortcomings of the clinical protocol were highlighted. Lastly, an attempt was made to provide a clinical test battery protocol based on the extracted protocol from the literature and clinical findings. Audiological tests and various factors that should have been used as a part of the clinical evaluation protocol for effective diagnosis and management of persons with tinnitus are proposed.

Chapter 4

RESULTS

The study aimed to identify the clinical test battery and its findings for persons with normal hearing sensitivity having tinnitus and compare it with the evidence from the literature. A total of twenty-seven case files were analysed retrospectively. The data was obtained from the case files, including the case history, different audiological tests administered, THI and their findings. The data obtained were descriptively analysed. The results are described under the following headings.

4.1 Demographic factors

Table 4.1 shows the demographic details of all the 27 subjects included in the study having unilateral (U/L) or bilateral (B/L) tinnitus with normal hearing sensitivity. All the subjects reported tinnitus as their primary complaint.

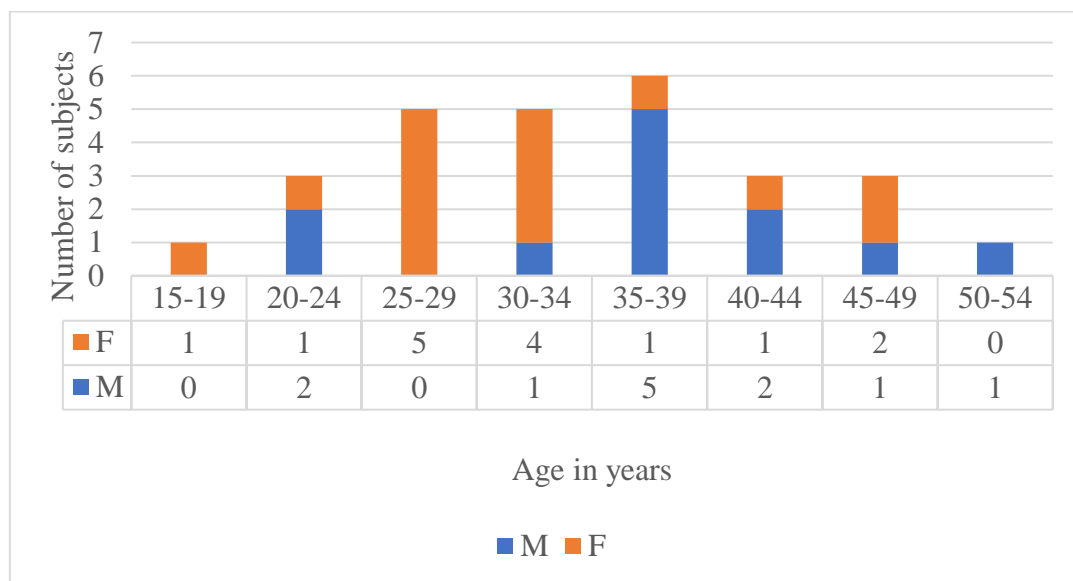
Table 4.1*Demographic details of the participants.*

Subject No.	Age in Years	Gender	Occupation
S1	25	F	Student
S2	20	M	Student
S3	27	F	Homemaker
S4	50	M	Self-employed
S5	35	M	Driver
S6	36	M	Cable operator
S7	35	M	Painter
S8	37	M	Coolie
S9	29	F	Diver
S10	39	M	Coolie
S11	41	M	Workshop
S12	31	F	Homemaker
S13	48	F	Teacher
S14	30	F	Homemaker
S15	25	F	Student
S16	25	F	Student
S17	45	F	Coolie
S18	40	F	Homemaker
S19	31	F	Teacher
S20	49	M	Sales manager
S21	31	F	Homemaker
S22	16	F	Student
S23	21	F	Student
S24	39	F	Homemaker
S25	30	M	Lecturer
S26	40	M	Student
S27	22	M	Student

The age of the subjects ranged from 16 years to 50 years (range: 34 years), with the majority of the subjects ($n=19$, 70.37%) in the second and third decade as represented in Figure 4.1. The mean age of the participants was 33.22 years, with a standard deviation of 9.14. Out of the 27 subjects, 15 (55.55%) were female, and 12 (44.44%) were male.

Figure 4. 1

Age and gender distribution of the participants.



The occupation of the subjects was diverse. Table 4.2 represents the occupation reported by all the subjects. Out of 27 subjects, 8 subjects (29.63%) were students, 6 subjects (22.22%) were homemakers.

Table 4.2*Occupational details of all the participants.*

Occupation	Number of subjects
Business	1
Cable operator	1
Coolie	2
Diver	1
Driver	1
Homemaker	6
Lecturer	1
Painter	1
Sales manager	1
Student	8
Teacher	2
Worker	1
Workshop	1
Total	27

4.2 Case history

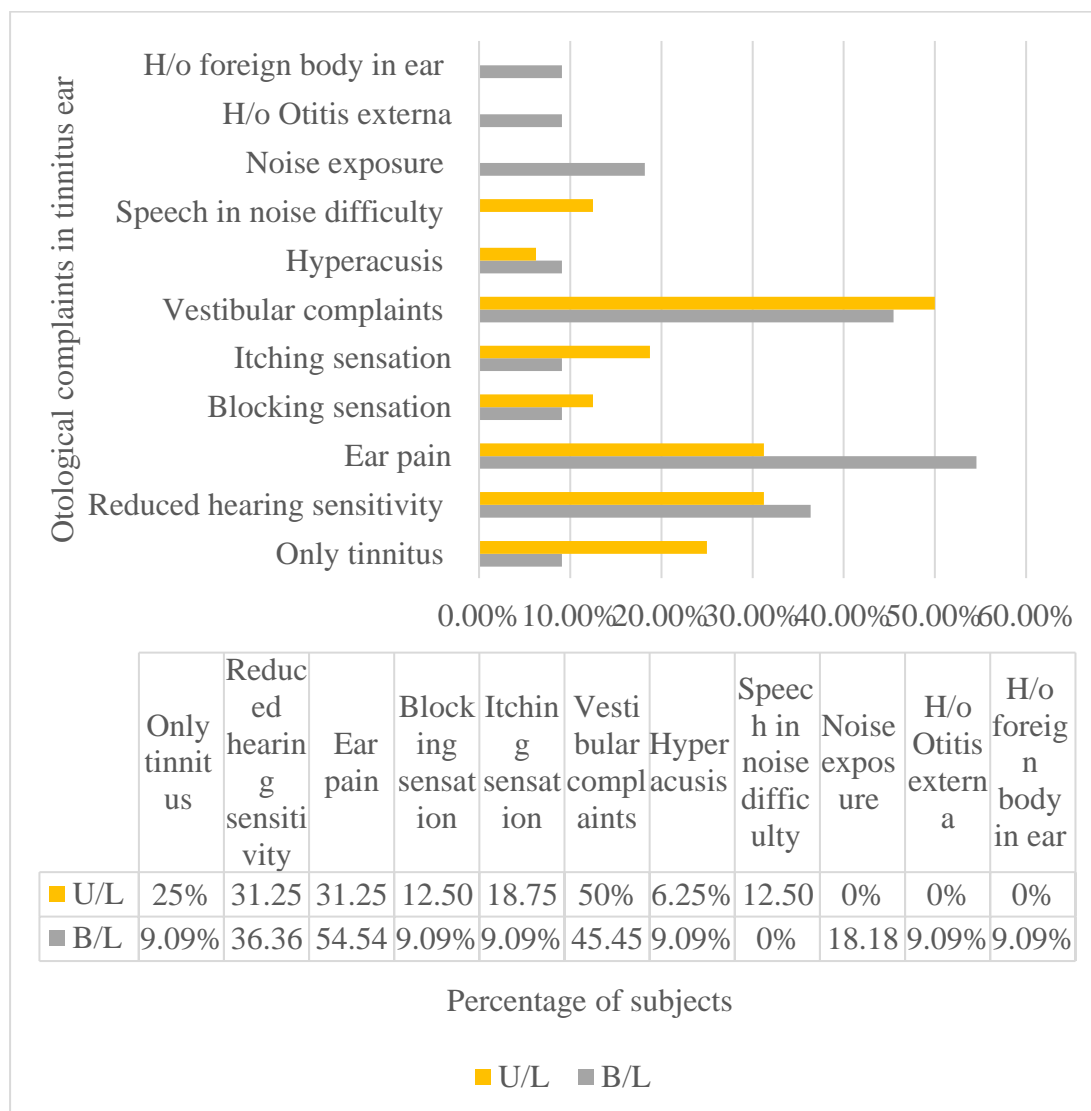
Each case underwent a comprehensive semi-structured interview, in which information regarding primary (otological) complaints, associated complaints and medical history was collected.

4.2.1 Otological complaints

Tinnitus was reported to be B/L by 11 subjects, and 16 subjects reported tinnitus to be U/L (R ear: 10, L ear: 6). The occurrence of associated complaints with tinnitus is shown in Figure 4.2.

Figure 4.2

Percentage of individuals reporting various otological complaints along with B/L and U/L tinnitus.



4.2.2 Non-otological complaints and Medical history

Non-otological complaints such as headache, frequent cold, the problem increased in the rainy season, vomiting and medical conditions like hypertension, diabetes mellitus, thyroid disease, orthostatic hypotension, allergic reactions, Upper Respiratory Tract Infection (URTI), and vestibular neuritis was reported by subjects. Table 4.3 represents the numbers and percentage of subjects having such conditions.

Table 4.3

Percentage of various non-otological complaints and medical history reported in subjects with B/L and U/L tinnitus.

S.no	Condition	B/L tinnitus	U/L tinnitus
1	Headache	1 (9.09%)	4 (25%)
2	Frequent cold	1 (9.09%)	3 (18.75%)
3	Vomiting	0	1 (6.25%)
4	Problem in rainy season/cold	0	2 (12.5%)
5	Hypertension	1 (9.09%)	1 (6.25%)
6	Diabetes mellitus	0	1 (6.25%)
7	Thyroid	0	1 (6.25%)
8	Allergic reaction	1 (9.09%)	2 (12.5%)
9	Orthostatic hypotension	1 (9.09%)	0
10	Vestibular Neuritis	1 (9.09%)	0
11	Upper respiratory tract infection	0	1 (6.25%)
12	Facial Palsy	0	1 (6.25%)
13	Resolved CSOM	0	1 (6.25%)

4.2.3 Description of tinnitus

During the case history, the subjects described the perception of tinnitus in terms of its characteristics, such as continuous or intermittent, high pitch or low pitch. The description of tinnitus is represented in Figure 4.3.

4.2.4 Duration of perception of tinnitus and the onset of tinnitus

The duration of tinnitus perception varied from 3 months to 5 years. Most subjects (9 subjects, 33.33%) reported perceiving tinnitus from 6 months to 1 year. The perception of tinnitus by subjects reporting bilateral and unilateral tinnitus is represented in Figure 4.4.

The onset of tinnitus and associated complaints were reported to be either gradual or sudden. Sudden onset was reported by 13 (48.14%) subjects (B/L tinnitus: 4 & U/L tinnitus: 9) while gradual onset was reported by 14 (51.86%) subjects (B/L tinnitus: 7 & U/L tinnitus: 7).

Figure 4.3

Subjective description of the tinnitus characteristics and pitch.

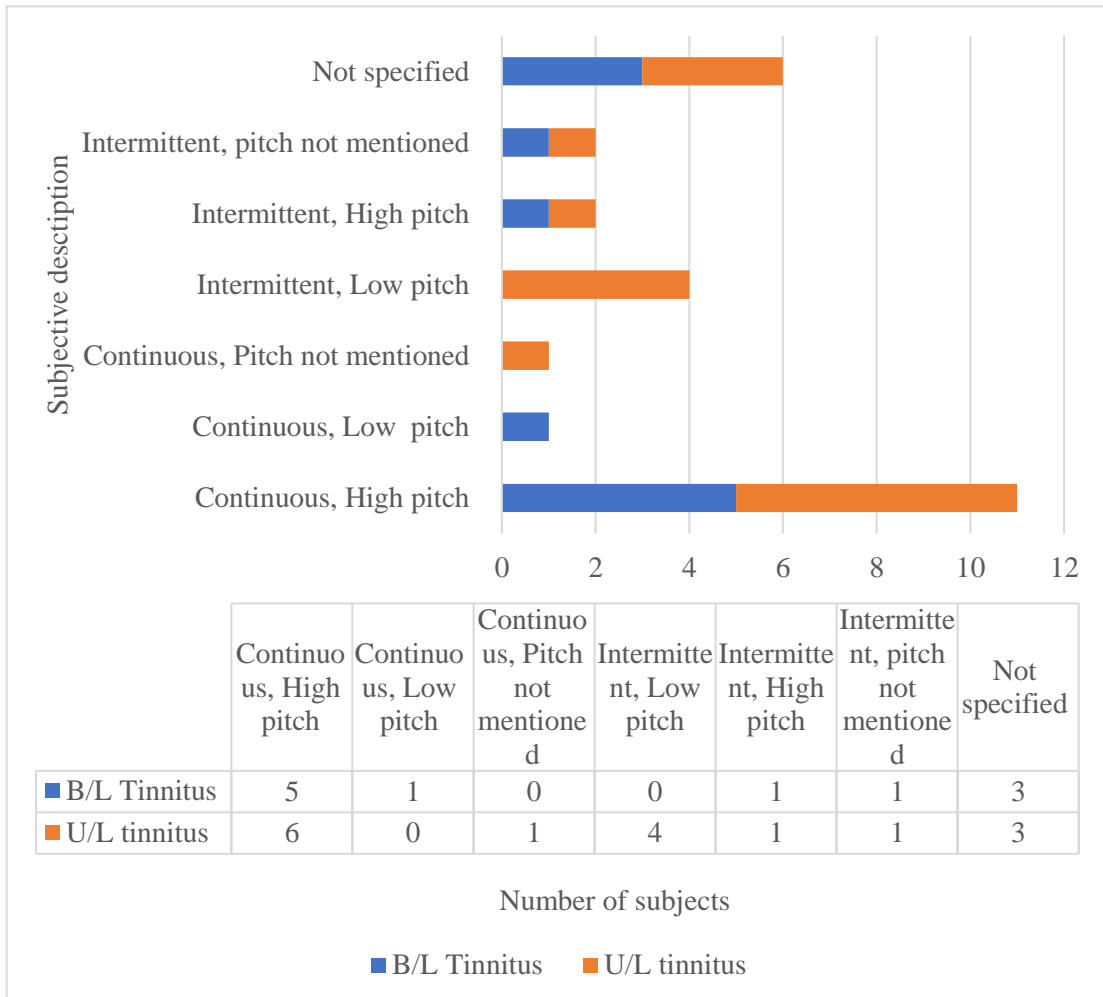
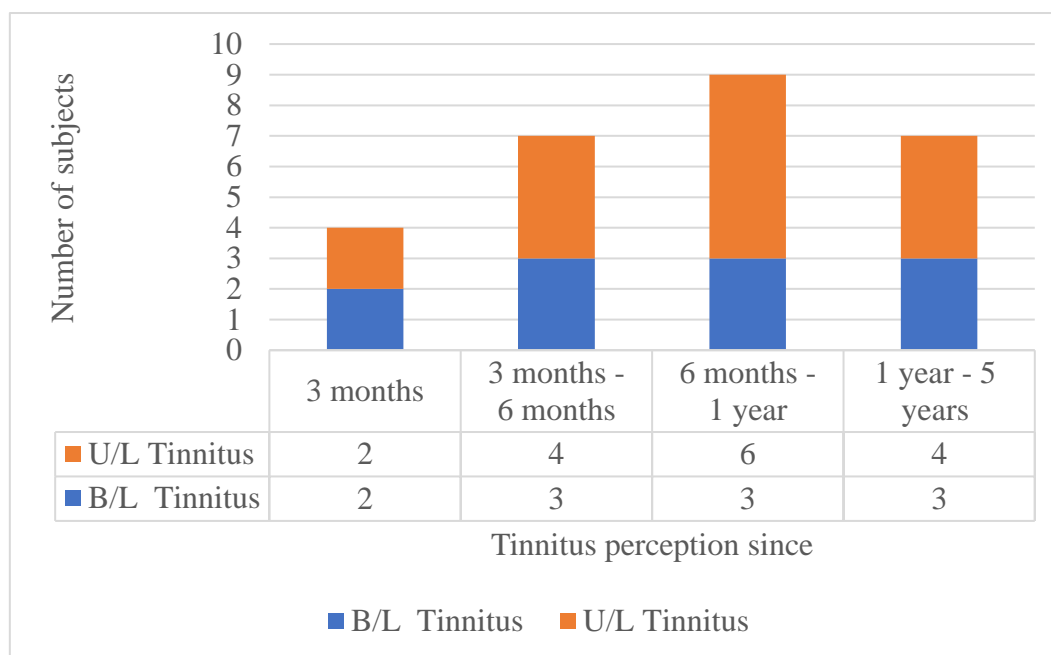


Figure 4.4

Duration of perception of tinnitus.



4.3 Audiological tests administered and findings

Various diagnostic tests are generally applied as a part of clinical test battery on a case-to-case basis. Each case was evaluated with a minimum test battery, and few additional diagnostic tests are done as and when required. The following information was tabulated, which included, Pure tone audiometry (PTA), Speech Audiometry, Uncomfortable level (UCL), Tympanometry, Acoustic reflex threshold testing (ART) (ipsilateral & contralateral reflexes) for all subjects. Audiological tests like the Reflex decay test, Oto-acoustic emissions (OAEs), and Auditory brainstem response (ABR), Speech in noise (SPIN), tinnitus matching and residual inhibition were not administered, hence findings of all these tests were reported from the available data.

4.3.1 Pure Tone Audiometry (PTA)

All the subjects in the study had undergone pure tone audiometry and had hearing sensitivity within normal limits. The pure tone average of four frequencies (500, 1000, 2000, 4000 Hz) was within 15 dBHL. In the bilateral tinnitus group, the mean right ear PTA was 8.75 dBHL with a standard deviation of 3.87 dBHL. The right ear PTA ranged from 3.75 dBHL to 13.75 dBHL (range: 10 dB). The Left ear mean PTA was 9.70 dBHL with a standard deviation of 4.34 dBHL. The left ear PTA ranged from 3.75 dBHL to 15 dBHL (range: 11.25).

In the unilateral tinnitus group, for the tinnitus ear, the mean and standard deviation of PTA was 9.76 dBHL and 3.26 dBHL, respectively. The PTA ranged from 3.75 dBHL to 15 dBHL (range: 11.25 dB) for the tinnitus ear. For the non-tinnitus ear, the mean and standard deviation was 8.29 dBHL and 2.90 dBHL, respectively. The PTA ranged from 2.5 dBHL to 12.5 dBHL (range: 10 dB).

Although the PTA was within 15 dBHL for both the ears for all the subjects and they were diagnosed as normal hearing sensitivity. However, there were morphologically significant variations in the audiogram which were clinically relevant. The important clinical manifestations observed were defined as slope, reverse slope, notch or flat configuration. Slope was defined as the hearing threshold difference of 10 dB or more between the extreme frequencies (250 Hz and 8 kHz) with the threshold of 8 kHz poorer than 250 Hz. Reverse Slope or rising pattern was defined as the hearing threshold difference of 10 dB or more with the threshold of 250 Hz poorer than 8 kHz. Notch was defined as thresholds poorer than adjacent frequencies by 10 dB or more at that particular frequency, and flat configuration was defined as a difference of 10 dB or less between thresholds at 250 and 8000 Hz. The presence of clinically relevant morphological factors is summarised in table 4.4.

Table 4.4

Morphological characteristics of pure tone threshold across frequencies.

Morphological characteristics	B/L tinnitus	U/L tinnitus
Sloping	2	2
Rising	2	2
4k notch	2	0
2k notch	0	1
Flat	5	11

4.3.2 Speech identification scores (SIS) in quiet and in noise

SIS for all the ears in all the subjects was 100%. Speech in noise (SPIN) was carried out at 0 dB SNR. SPIN was considered affected if the score reduction was more than 40 % from SIS (obtained in quiet). SPIN data was available only for 5 subjects (bilateral tinnitus: 2 subjects and unilateral tinnitus: 3 subjects). All the subjects showed normal SPIN scores for both the ears.

4.3.3 Uncomfortable level (UCL)

UCL data was not available for 2 subjects with bilateral tinnitus. For the remaining 25 subjects, UCL ranged from 85 dBHL to >100 dBHL. For subjects reporting bilateral or unilateral tinnitus, UCL was the same for both ears. UCL was most commonly >100 dBHL in 18 subjects, 100 dBHL in 4 subjects, 85 dBHL in 1 subject, 90 dBHL in 1 subject and 95 dBHL in 1 subject. UCL was not available for 2 subjects.

4.3.4 Immittance Evaluation

All the subjects underwent tympanogram and acoustic reflex testing using a standard 226 Hz probe tone. Subjects with tympanogram types other than "A/A_s" were excluded from the study to rule out any middle ear abnormality.

The acoustic reflex threshold was tested both ipsilaterally and contralaterally at 500 Hz, 1 kHz, 2 kHz, and 4 kHz. For the present study, reflexes were analysed as present or absent in both ipsi and contra mode. Both ipsi and contra reflexes were present at all frequencies for all cases except for three cases. Out of the three subjects, one with unilateral tinnitus showed an absence of contra reflexes at all frequencies bilaterally and an absence of 2 kHz and 4 kHz ipsi reflexes in the tinnitus ear. One subject with bilateral tinnitus showed an absence of ipsi and contra reflexes in the left ear. Another subject with bilateral tinnitus had present ipsi reflexes but absence of contra reflexes in the right ear.

4.3.5 Reflex Decay Test (RDT)

Of the 27 subjects, RDT was included in the test battery for 5 subjects only (bilateral tinnitus: 1 subject, unilateral tinnitus: 4 subjects). All the 5 subjects revealed negative RDT.

4.3.6 Oto-Acoustic Emissions (OAE)

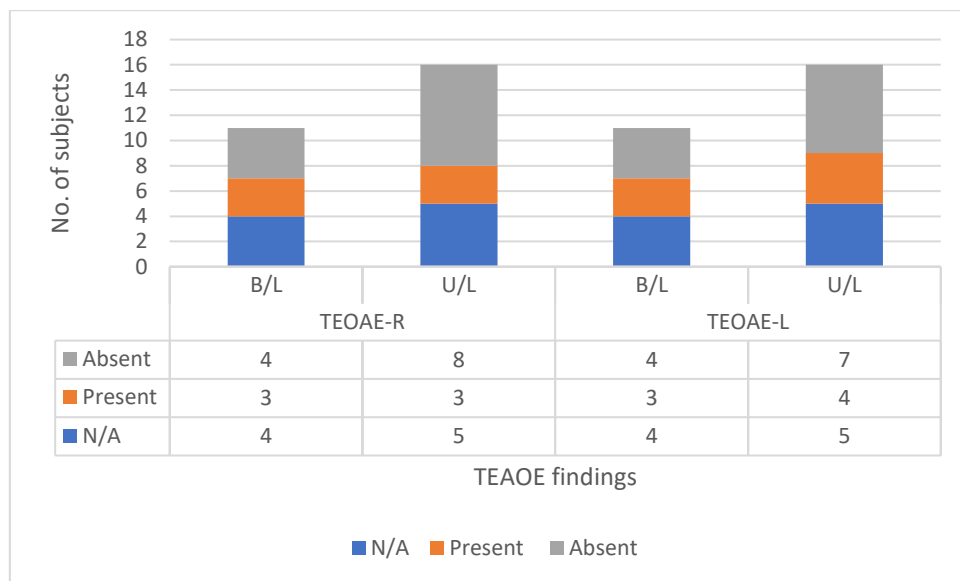
Transient- Evoked Oto -Acoustic Emissions (TEOAE) and/or Distortion Product Oto-Acoustic Emissions (DPOAE) was administered and were considered to be present if the SNR was ≥ 6 dB for three consecutive frequencies and reproducibility of $\geq 90\%$. It was considered absent if the SNR criteria and/or reproducibility criteria did not meet. For every case initially, TEAOE was done; if TEAOE was absent, then only DPOAE was measured.

OAE was not done for nine subjects (bilateral tinnitus: 4 subjects, unilateral tinnitus: 5 subjects). For the remaining 18 subjects, TEAOE was evaluated bilaterally. Out of 18 subjects (bilateral tinnitus: 7 & unilateral tinnitus: 11) TEAOE in right ear was present in 6 subjects (33.33%) (bilateral: 3 & unilateral: 3) and absent in 12 subjects

(66.66%) (bilateral tinnitus: 4 & unilateral tinnitus: 8). TEOAE in left ear was present in 7 subjects (38.89%) (bilateral: 3 & unilateral: 4) and absent in 11 subjects (61.11%) (bilateral tinnitus: 4 & unilateral tinnitus: 7) as depicted in the Figure 4.5

Figure 4.5

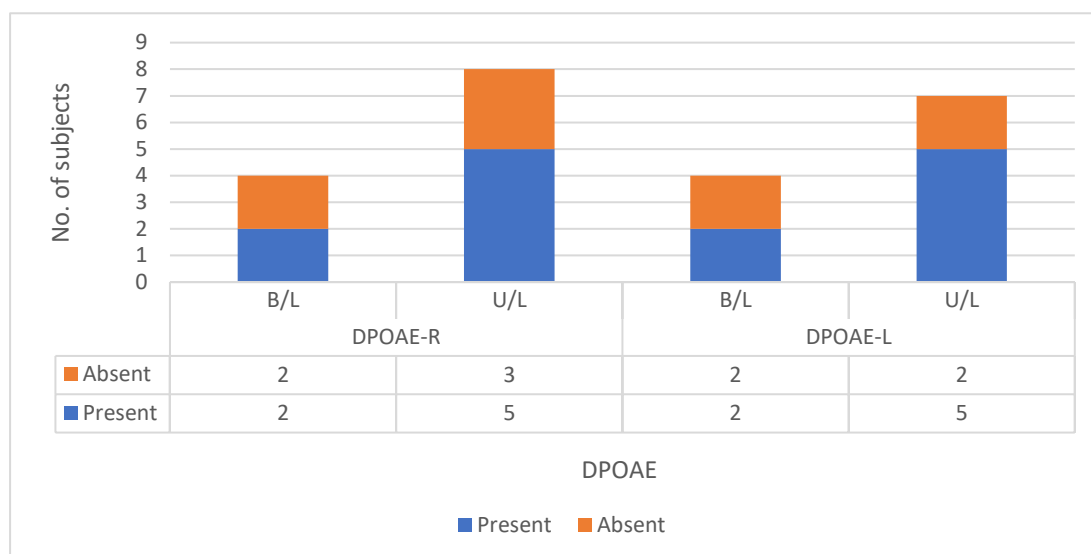
Ear-specific TEOAE findings in B/L and U/L tinnitus subjects.



For subjects with absent TEAOE (right ear:12 & left ear: 11), DPOAE was evaluated. Out of 12 subjects having TEAOE absent in the right ear, DPOAE was present and absent in 7 subjects (58.33%) and 5 subjects (41.67%), respectively. Out of 11 subjects with TEAOE absent in the left ear, DPOAE was present and absent in 7 subjects (63.64%) and 4 subjects (36.36%), respectively, as shown in Figure 4.6.

Figure 4.6

Ear-specific DPOAE findings in B/L and U/L tinnitus subjects.



4.3.7 Auditory Brainstem Response Site of Lesion (ABR- SOL)

ABR-SOL was carried out using clicks stimuli at low and high repetition rates. Latency of I, III and V peak was mentioned in the case file. Based on the latency values, ABR-SOL was considered to be positive (indication of RCP) if the interpeak latency difference (IPLD) was more than 2 ms, or if no identifiable V peak was present at a high repetition rate, or if the interaural difference (IALD) of V peak latency was ≥ 0.4 ms.

ABR-SOL was done only for 9 subjects (33.33%) (bilateral tinnitus: 5 & unilateral tinnitus: 4). ABR-SOL was negative (no indication of RCP) for 5 subjects (55.56%) (bilateral tinnitus: 3 & unilateral tinnitus: 2). Four subjects (44.44%) (bilateral tinnitus: 2 & unilateral tinnitus: 2 subjects) showed positive ABR-SOL results. The findings of ABR-SOL are summarised in table 4.5.

Table 4.5*ABR-SOL findings.*

ABR-SOL findings	B/L	U/L
N/A	6	12
Negative	3	2
POS: increased IPLD > 2ms	1	0
POS: no V peak at high RR	1	1
POS: IALD >0.4ms	0	1

4.3.8 Tinnitus Matching and Residual Inhibition

Tinnitus matching for identifying the pitch and loudness of tinnitus was carried out using an audiometer. The subject was supposed to match the pitch and the loudness of the tinnitus in one ear to the external tone/noise presented in the other ear. Residual inhibition was assessed by presenting a noise for 1 minute. Residual inhibition was termed positive if tinnitus perception was eliminated entirely after exposure to noise for one minute. Partially positive if the perception of tinnitus was reduced in terms of its loudness for some time. Negative if no change was reported in tinnitus perception and rebound if tinnitus perception increased after the noise presentation.

Tinnitus matching data for frequency was not done for 15 subjects, and the remaining 12 subjects (bilateral tinnitus: 5 & unilateral tinnitus: 7) it was carried out. Two subjects could not match tinnitus with pure tone or NBN of any frequency. Six subjects matched tinnitus with continuous pure tone, 3 matched tinnitus with NBN and 1 matched tinnitus with pulsed pure tone. Tinnitus loudness matching data was not done for 16 subjects. The remaining 11 subjects (bilateral tinnitus: 4 & unilateral tinnitus: 7) reported loudness to vary from 10 dBHL to 65 dBHL.

Residual inhibition was assessed for only 11 subjects (bilateral tinnitus: 4 & unilateral tinnitus: 7). Residual inhibition was positive for 5 subjects, partial for 4 and

negative for 2 subjects. Table 4.6 represents data of tinnitus pitch matching, loudness matching and residual inhibition.

Table 4.6

Findings of tinnitus frequency and intensity matching and residual inhibition.

Frequency (Hz)	No of subjects	Intensity match (dBHL)	No of subjects	Residual Inhibition	No. of subjects
125	2	10	3	N/A	16
250	2	20	2	Negative	2
500	1	25	3	Partial	4
3000	1	30	1	Positive	5
4000	1	40	1		
8000	3	65	1		
Can't be matched	2	N/A	16		
N/A	15				

4.4 Relationship between various factors

4.4.1 Relationship between occupation and type of tinnitus

Tinnitus pitch (available for 12 subjects) was classified based on the pitch into three categories viz., low-pitch (≤ 2 kHz), high-pitch (>2 kHz), and cannot be matched with any frequency. Loudness matching (available for 11 subjects) was categorised as mild (<25 dBHL), moderate (25-40 dBHL) and severe (>40 dBHL). The results of tinnitus pitch and loudness matching were compared with the occupation (Table 4.7). The tinnitus pitch and loudness were also compared with various associated otological and non-otological conditions (Table 4.8).

Table 4.7

Relationship between occupation vs type of tinnitus.

Tinnitus type	Student (n=8)	Homemaker (n=6)	Other (n = 13)
Frequency			
Low pitch (n=5)	1	2	2
High pitch (n=5)	3	0	2
Cannot be matched (n=2)	0	0	2
Loudness			
Mild (n= 5)	2	1	2
Moderate (n=5)	2	1	2
Severe (n=1)	0	0	1

Note: Not all subjects had tinnitus pitch, loudness and residual inhibition. Out of 8 students, only 4 had undergone pitch and loudness matching. Similarly, for homemakers, only 2 had undergone pitch and loudness match. In other occupations, only 6 individuals had pitch matching, and only 5 had loudness matching data available.

From Table 4.7, it is clear that subjects had different perceptions of tinnitus from all occupations. The perception of tinnitus varied within the occupation, and there was no dominant pitch or loudness across occupation.

4.4.2 Relationship between the type of tinnitus and associated complaints

Various otological and non-otological complaints were reported by all the individuals. The complaints were grouped into different categories and were compared with tinnitus pitch and loudness reported.

Table 4.8

Occurrences of various otological and non-otological factors in individuals with different tinnitus pitch and loudness.

Otological complaints other than T	Low-pitch (n=5)	High-pitch (n=5)	Cannot be matched (n=2)	Mild (n=5)	Mod- erate (n=5)	Seve- re (n=1)
· NCR	1	3	1	1	3	0
· RHS	1	1	1	1	1	1
Otological conductive						
· Ear Pain	2	1	1	2	1	0
· Blocking Sensation	0	0	0	0	0	0
· Itching Sensation	1	0	0	1	0	0
Otological cochlear						
· Hyperacusis	0	0	0	0	0	0
Otological RCP						
· Speech understanding difficulty	1	0	0	1	0	0
· Vertigo	2	2	0	2	0	1
Medical Otological conditions						
· Frequent cold	1	0	0	1	0	0
· Resolved CSOM	1	0	0	0	1	0
· URTI	1	0	0	0	1	0
· Problem in rainy season	0	0	0	0	0	0
· H/o Otitis Externa	0	0	0	0	0	0
· H/o foreign body in ear	1	0	0	0	0	0
· Noise exposure	0	0	1	0	0	0
· Allergy	1	0	0	1	0	0
Vestibular conditions						
· Vestibular neuritis	0	0	0	0	0	0
· Meniere's disease	0	0	0	0	0	0
· Orthostatic Hypotension	0	0	0	0	0	0
Neurological conditions						
· LMN Facial Paralysis	1	0	0	0	1	0
General health						
· Hypertension	0	0	0	0	0	0
· Diabetes mellitus	0	1	0	0	1	0
· Thyroid	0	0	1	0	1	0
· Headache	0	0	1	0	1	0
· Vomiting	0	0	0	0	0	0

Note: Each subject had the presence of one or more than one associated factor.

From table 4.8, it can be concluded that tinnitus was associated with a heterogenous clinical profile. The majority of the subjects had at least one otological condition or other non-otological condition. Three subjects with high pitch tinnitus reported no other complaint than tinnitus, suggesting tinnitus can be cochlear phenomenon. For people reporting any medical condition associated with the external or middle ear, low-pitch tinnitus was reported.

4.4.3 Relationship between audiological findings and type of tinnitus

Few tests did not show any significant deviant findings between the subjects. These tests include SIS, SPIN, UCL, tympanogram, ART (ipsilateral & contralateral) and RDT. The tests that had significant differences in findings and the type of tinnitus are summarised in Table 4.9.

Table 4.9*Audiological tests' findings and tinnitus pitch and loudness matching*

Audiological tests and its findings	Low-pitch (n=5)	High-pitch (n=5)	Frequency Cannot be matched (n=2)	Mild (n=5)	Mode rate (n=5)	Severe (n=1)
PTA						
• Flat	3	2	0	4	2	0
• Sloping	1	2	1	1	2	0
• Rising	1	1	0	0	1	1
• Notch	0	0	1	0	0	0
TEOAE						
• Present	3	2	0	2	3	0
• Absent	2	2	2	2	2	1
• Not measured	0	1	0	1	0	0
DPOAE (if TEOAE absent)						
• Present	2	0	1	2	1	0
• Absent	0	2	1	0	1	1
• Not measured	0	0	0	0	0	0
ABR-SOL						
• Positive	0	2	0	1	1	0
• Negative	0	0	1	0	0	0
• Not done	5	3	1	4	4	1

It can be concluded from Table 4.9 that the pattern of audiogram was associated with all types of tinnitus and no tinnitus type had dominant morphological characteristics of PTA. TEOAE was absent and present for few individuals in each type of tinnitus. For the subjects with absent TEOAE, DPOAE was present in subjects reporting low-pitch tinnitus and absent in subjects with high-pitch tinnitus. ABR-SOL was positive in only two subjects, and both subjects had high-pitch tinnitus.

4.5 Clinical Evaluation Protocol

Various diagnostic tests were used to arrive at a differential diagnosis, identify pathophysiology, and provide appropriate counselling and management. Table 4.10 summarises the various audiological tests administered as a part of the clinical assessment protocol.

Table 4.10

Audiological evaluation protocol used for individuals with tinnitus having normal hearing.

Subject	Age/Sex	Tinnitus	PTA	Speech Audiometry	SPIN	UCL	Tympanogram	ART	RDT	OAE	ABR-SOL	Tinnitus Matching	Residual inhibition	THI
S1	25/F	B/L	✓	✓	✓	✓	✓	✓	✓	✗	✓	✗	✗	✗
S2	20/M	B/L	✓	✓	✗	✓	✓	✓	✗	✓	✓	✓	✓	✗
S3	27/F	B/L	✓	✓	✗	✓	✓	✓	✗	✓	✗	✗	✗	✗
S4	50/M	B/L	✓	✓	✗	✓	✓	✓	✗	✓	✓	✗	✗	✗
S5	35/M	B/L	✓	✓	✗	✓	✓	✓	✗	✗	✗	✗	✗	✗
S6	36/M	B/L	✓	✓	✗	✓	✓	✓	✗	✗	✗	✗	✗	✗
S7	35/M	B/L	✓	✓	✗	✗	✓	✓	✗	✓	✗	✓	✓	✗
S8	37/M	B/L	✓	✓	✗	✗	✓	✓	✗	✓	✗	✓	✓	✗
S9	29/F	B/L	✓	✓	✓	✓	✓	✓	✗	✗	✓	✗	✗	✗
S10	39/M	B/L	✓	✓	✗	✓	✓	✓	✗	✓	✗	✗	✗	✗
S11	41/M	B/L	✓	✓	✗	✓	✓	✓	✗	✓	✓	✓	✓	✗
S12	31/F	R	✓	✓	✗	✓	✓	✓	✓	✓	✗	✓	✗	✗
S13	48/F	R	✓	✓	✗	✓	✓	✓	✗	✗	✓	✗	✗	✗
S14	30/F	R	✓	✓	✗	✓	✓	✓	✗	✓	✗	✓	✓	✗
S15	25/F	R	✓	✓	✗	✓	✓	✓	✓	✓	✗	✓	✓	✗
S16	25/F	R	✓	✓	✗	✓	✓	✓	✗	✓	✗	✓	✓	✗
S17	45/F	R	✓	✓	✗	✓	✓	✓	✗	✓	✗	✗	✗	✗
S18	40/F	R	✓	✓	✗	✓	✓	✓	✓	✓	✗	✗	✗	✗
S19	31/F	R	✓	✓	✗	✓	✓	✓	✗	✓	✗	✓	✓	✗
S20	49/M	R	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓
S21	31/F	R	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✗
S22	16/F	L	✓	✓	✓	✓	✓	✓	✗	✗	✗	✗	✗	✗
S23	21/F	L	✓	✓	✗	✓	✓	✓	✓	✗	✗	✓	✓	✗
S24	39/F	L	✓	✓	✗	✓	✓	✓	✗	✓	✓	✗	✗	✗
S25	30/M	L	✓	✓	✗	✓	✓	✓	✗	✓	✓	✗	✗	✗
S26	40/M	L	✓	✓	✗	✓	✓	✓	✗	✗	✗	✗	✗	✗
S27	22/M	L	✓	✓	✗	✓	✓	✓	✗	✗	✗	✗	✗	✗

The components of the clinical evaluation protocol and its findings can be summarised as:

1. All the subjects audiological evaluation compulsorily including but not limited to PTA, Speech audiometry, UCL, tympanometry and ART.
2. Though tinnitus was the primary complaint and all subjects should have undergone tinnitus matching and residual inhibition, only 12 subjects had undergone tinnitus matching.
3. SPIN was administered only for 5 subjects, and all subjects had normal SPIN scores.
4. Objective diagnostic tests included RDT, OAE evaluation & ABR-SOL were administered for 5 subjects, 18 subjects and 9 subjects, respectively.
5. For OAE measures, TEOAE was measured first. In absent TEOAE, DPOAE was measured.
6. Although all subjects had normal hearing sensitivity, PTA showed important morphological characteristics such as sloping, rising & notching in 11 (40.74%) out of 27 subjects.
7. Interestingly, TEOAE was absent in 12 (66.66%) of the 18 subjects bilaterally. Irrespective of whether tinnitus was unilateral or bilateral.
8. In 12 subjects with absent TEAOE, DPOAE was present & absent in 7 subjects (58.33%) & 5 subjects (41.67%) respectively.
9. ABR-SOL was positive in 4 (44.44%) out of 9 subjects.
10. THI score was available only for one individual with a moderate handicap (Grade 3).

11. In addition to the above-mentioned tests, all subjects underwent a minimum assessment, including a semi-structured interview for case-history interview and ENT evaluation also.

4.6 Comparison between existing protocol available in the literature and clinical protocol used for assessment

The selected study comprised of three studies (study 1, 2 & 4) with level 1 of evidence (systematic review of RCTs) and two studies (study 3 & 5) were of lower-level but included because they were the expert review of tinnitus assessment and management of tinnitus based on evidence-based guidelines. All the studies strongly recommended a multidisciplinary assessment of tinnitus. Physical examination of the ear by an otolaryngologist and audiological examination, identification of individuals with bothersome tinnitus, use of tinnitus and its impact related questionnaires was recommended by all guidelines. Referral for psychological assessment was recommended whenever required, by all guidelines. All guidelines strongly recommended targeted and detailed case history concerning tinnitus. Guidelines Variations existed in the use of imaging techniques such as MRI and/or CT-SCAN. The recommended evaluation guidelines differed based on specific procedures (questionnaires, diagnostic tests, and types of scanning or imaging techniques) rather than the basic assessment principle.

Specific audiological tests recommended for the clinical evaluation protocol were provided only in 3 studies. The other two guidelines provided no specific audiological tests but were strongly recommended for comprehensive audiological evaluation. The protocol of three studies used for assessment is summarised in table 4.11 for comparison.

It can be concluded that all the guidelines recommended for tinnitus targeted case-history, ENT evaluation and audiological evaluation. All the guidelines recommended using PTA, SIS, Tympanogram, tinnitus-related questionnaire, OAE measures, tinnitus matching and residual inhibition. Study 3 recommends adding 3kHz and 6 kHz in pure tone audiometry. Reflex measurements were advised to be done with caution of high-intensity sound, especially in persons reporting Decreased Sound Tolerance and recent changes in tinnitus perception. None of the guidelines recommends RDT.

Table 4.11

Evaluation protocol as reported in three different studies.

Specific Audiologic tests	Study 1	Study 2	Study 3
PTA	✓	✓	✓ ^e
EHFA	✓	✗	✓
SIS	✓	✓	✓
SPIN	✗	✗	✗
UCL	✓ ^d	✓	✓ ^d
Tympanogram	✓	✓	✓
ART	✓	✓	✗
RDT	✗	✗	✗
TEOAE	✓ ^a	✓	✓
DPOAE	✓ ^a	✓	✓ ^b
ABR-SOL	✓ ^c	✓ ^c	✗
Tinnitus Frequency Matching	✓	✓	✓
Tinnitus Loudness Matching	✓	✓	✓
Residual inhibition	✓	✓	✓
Tinnitus related questionnaire	✓	✓	✓
Vestibular Evaluation	✓	✓	✓

Note: a: especially for normal hearing b: 1 to 10 kHz with 6 to 8 points per octave c: for U/L tinnitus only d: UCL to be tested with caution. e: including thresholds at 3 and 6 kHz.

In the cases of normal conventional hearing threshold, EHFA was recommended by 2 guidelines (study 1 and study 3). TEOAE and DPOAE are recommended by studies 1 and 3, especially for normal hearing, and also study 3 stressed on including DPOAE from 1 to 10 kHz using 6 to 8 points per octave. ABR-

SOL was recommended in the case of U/L tinnitus only. Vestibular evaluations are recommended if vestibular problems are reported. Study 1 recommended using a tinnitus grading system in case history and administering a tinnitus-related questionnaire for individuals with Grade 2 or more. Feldman's masking curve was recommended by study 2. No other guidelines mentioned about the masking curves.

On comparison of clinically used protocol and recommended protocol from the literature, it can be highlighted that clinical evaluation protocol consisted of major tests recommended by literature except for EHFA, DPOAE fine structure and tinnitus-related questionnaire. However, the inconsistency in the use of subjective and objective tests such as tinnitus matching, OAE and ABR-SOL was observed. SPIN and RDT were also used in clinics or few subjects, but any of the guidelines do not recommend them.

Chapter 5

DISCUSSION

5.1 Clinical test battery

The study's first objective was to identify the clinical evaluation protocol for persons with normal hearing sensitivity having tinnitus and determine the various tests administered as part of the routine audiological evaluation. As depicted in Table 4.11, various audiological tests administered for evaluating individuals with tinnitus having normal hearing consisted of basic audiological evaluation and various subjective/objective diagnostic tests for differential diagnosis. Basic audiological evaluation (PTA, speech audiometry, UCL, tympanogram and ART) was carried out for all subjects. Many tests, including OAE, ABR-SOL, RDT, tinnitus matching and residual inhibition, were administered only for few subjects. Few tests, including SIS, SPIN, UCL, tympanogram, ART (ipsilateral & contralateral) and RDT, did not show any significant deviant findings between the subjects and were well within clinical normative followed. Other tests had significant differences in findings (Table 4.9). From an audiologist standpoint, the approach to the assessment of tinnitus compromises causal diagnostics and severity-oriented diagnostics. The audiologist's role is to identify any possible cause of tinnitus, carry out a comprehensive audiological evaluation, identify persons with bothersome tinnitus and make appropriate referrals accordingly. Audiologists should also provide counselling and education about tinnitus and available management options (as indicated). With a few adjustments, the test battery used to evaluate most of the day-to-day cases can simply be adapted for individuals with tinnitus having normal hearing.

5.2 Associated conditions and their relationship with tinnitus

The presence of various otological and non-otological factors in 81% of subjects (Figure 4.2) highlights the fact that it is a symptom associated with various conditions. From table 4.8, it is evident that the majority of the subjects had at least one otological condition or other non-otological condition. These conditions can be categorised as otological, neurological, traumatic, cardiovascular, orofacial, psychological, immunological, endocrinal, metabolic disorders and pharmacological factors (Baguley et al., 2013; Cima et al., 2019). The presence of a myriad of symptoms with tinnitus underlines the importance of viewing tinnitus as a result of complex interactions rather than only as an isolated symptom.

In the present study, tinnitus was most commonly associated with vestibular symptoms in 50% of subjects with unilateral tinnitus and 45.45 % of subjects with bilateral tinnitus. In literature, it has been reported that many individuals with tinnitus who do not complain about vertigo have abnormal vestibular test results (Seabra & Diamantino, 1995; Shulman, 1991). It has also been reported that tinnitus is often the initial sign of Ménière's disease, and it might appear months or years before the other symptoms appear (Tokumasu, Fujino, Naganuma, Hoshino & Arai, 1996). Thirty-three percent of subjects reported reduced hearing sensitivity, although they all had thresholds within normal limits. Tinnitus of any type indicates some problem in the ear and/or peripheral or central nervous system. Tinnitus with normal hearing can be the first symptom of a hearing-related disorder which can be diagnosed once the threshold deteriorates. Headache was also reported by five subjects with tinnitus. There is a possible link between migrainous headache and tinnitus. Recent findings identified a link between migraine and tinnitus in young people, with the strongest link found in the migraine with aura subgroups (Guichard, Montagni, Tzourio & Kurth, 2016). For

people reporting any medical condition associated with the external or middle ear, low-pitch tinnitus was reported.

In contrast, the subject reporting high-pitch tinnitus did not have the presence of any complaint pertaining to the middle or external ear. According to Jastreboff (2011), about 75% of new cases are related to emotional stress as the trigger factor. There was no such factor reported in the case files, which might be due to inefficient case-history interview. Although we are not sure about the etiology of tinnitus individually, research establishes few contributing factors which can lead to tinnitus perception. Other than associated otological problems, cardiovascular, psychological, neurological, musculoskeletal, and nutritional issues have been linked to tinnitus (Deklerck, Debacker, Keppler & Dhooge, 2020). The high variability within and between different tinnitus individuals necessitates a multidisciplinary assessment of tinnitus.

5.3 Critical evaluation of clinical assessment protocol and literature recommended protocol

. The findings of the clinically administered protocol were compared, and shortcomings of the protocol were identified after comparison with literature. The critical comparison of the clinical vs evidence-based recommended protocol is discussed under the following headings. Based on this comparison protocol for assessment of individuals with tinnitus having normal hearing is recommended.

5.3.1 Multidisciplinary assessment

The clinical protocol followed in AIISH followed the multidisciplinary approach for assessment, including compulsory evaluation by an Otolaryngologist and Audiologist. A minimum assessment of individuals reporting chronic tinnitus by an otolaryngologist and audiologist is strongly recommended by all the guidelines

considered. To conclude for evaluating tinnitus should include Otolaryngologist, Audiologist, Psychologist, Neurologist, and General physician referred to as required (Fuller et al., 2017).

5.3.2 Case history

The clinical protocol used in AIISH for case history included the major components as depicted in results, including demographic details (Table 4.1), identifying the site of tinnitus and associated otological and non-otological conditions (Figure 4.2 & Table 4.3), description of characteristics of tinnitus (Figure 4.3), onset (Table 4.4) and perception of tinnitus since (Figure 4.4). However, the clinical case history failed to identify any triggering factor, modulating factors and history of long term pharmaceutical dosage (for disorders other than hypertension & diabetes mellitus). Description of tinnitus characteristics and its onset was not consistently elicited for all individuals.

In the case-history evaluations, the severity of tinnitus perception and its impact on QOL was not evaluated in any subject. It has been reported that in persons with normal hearing, tinnitus is known to cause greater annoyance compared to persons with tinnitus having hearing loss (Martines et al., 2010a). Suggesting the impact of tinnitus in normal hearing can be elicited by or lead to a certain degree of psychological distress such as anxiety, depression, and irritability. Similarly, it is believed that tinnitus is less related to age and comorbidities in people with normal hearing and more related to psychological or emotional problems like depression and stress (Choi, Lee & Kim, 2021).

In order to collect the necessary information for understanding the etiology, pathophysiology and selecting therapeutic care, a comprehensive case history must be undertaken for all individuals with tinnitus (Langguth et al., 2011). Targeted case

history helps reduce expense and administrative load, streamline the approach, and improve the time-efficiency of further assessment (Cima et al., 2019). According to available evidence from all the guidelines, targeted tinnitus history is the most important step in assessing tinnitus. Hence, it is recommended to include targeted tinnitus history in the case history for assessing tinnitus, especially for persons with normal hearing. Special consideration should be kept in mind for identifying persons with bothersome tinnitus and associated negative reactions to perception of tinnitus.

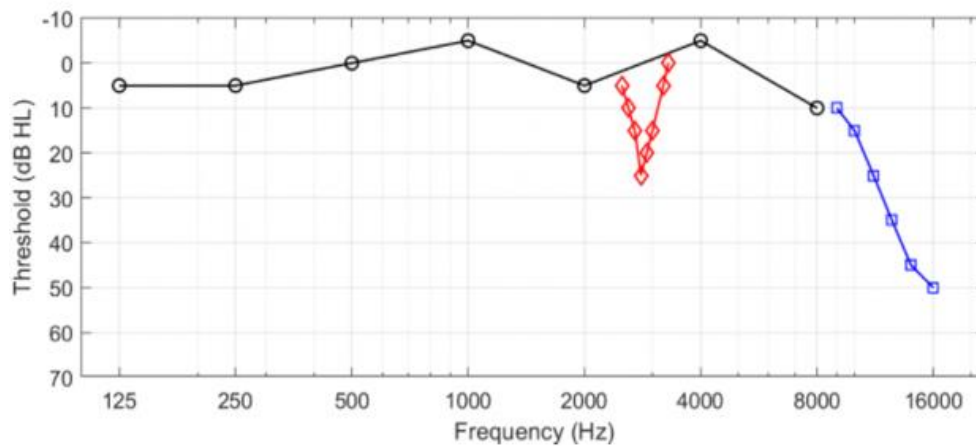
5.3.3 Pure tone Audiometry (PTA)

Despite all the subjects having normal hearing sensitivity, the presence of a sloping pattern in 14.81%, the rising pattern in 14.81% and presence of 4kHz notch in 7.40% and the presence of 2k notch in 7.40% of subjects (Table 4.4) highlights the fact that cochlear pathology is not always expressed in the routine audiogram but may be detected by more sensitive measures. The word "normal hearing sensitivity" should be used carefully. Normal hearing is an arbitrary term, anyone having a PTA of < 15 dBHL, 20 dBHL thresholds at 4 kHz, and 40dBHL at 8kHz is pathological and not normal hearing sensitivity. The presence of slope or notch indicates a localised problem, not affecting the hearing threshold at other frequencies.

There are several ways the conventional octave-based pure tone audiometry might miss the associated hearing problem as depicted in the audiogram in figure 5.1 presence of notch at interoctaves and extended high-frequency region questions the sensitivity of PTA. Studies using fine structure audiometry (1/24 per octave) have found notched audiograms in persons with otherwise normal hearing (Xiong, Liu, Liu, Peng, Lin, and Sun, 2019).

Figure 5.1

Two possible ways in which octave-based conventional pure tone audiogram can miss the hearing loss. Red colour shows how a notch at a frequency other than an octave frequency can be missed. Blue colour shows that poor hearing abilities in the Extended-high-frequency range can be missed.



Study 3 recommended measuring the hearing threshold at 3 kHz and 6 kHz in cases with normal conventional audiograms. Based on the presence of important clinical markers in the persons reporting to AIISH having tinnitus with normal hearing sensitivity and evidence from the literature, it is recommended to measure the threshold at 3 kHz, and 6 kHz and care must be taken in identifying individuals with morphological characteristics from audiogram like slope, reverse slope and notch.

5.3.4 Extended High-Frequency Audiometry (EHFA)

EHFA was not included in the clinical evaluation as a part of the test battery for any subject with normal hearing sensitivity reporting tinnitus. Many people's hearing sensitivity falls within normal ranges when assessed using traditional audiometry procedures. With respect to various researches, it can be concluded that extended high-frequency audiometry provides additional information on the cochlear status in people who have tinnitus with otherwise normal hearing sensitivity. OHC damage and increased hearing thresholds in the extended high-frequency area are seen in individuals

with tinnitus having normal hearing. (Fabijańska et al., 2012; Shim et al., 2009; Sreeraj, 2017).

In the evidence-based assessment protocol, EHFA is recommended by two guidelines (study 1 and study 2), especially for normal hearing. Sreeraj (2017) has also found significantly poor ultra high-frequencies for persons with normal hearing thresholds at conventional frequencies. Hence, it can be concluded that high-frequency audiometry is an effective instrument for diagnosing the presence of early cochlear pathology in those who suffer from tinnitus and should be included as a part of audiological evaluation protocol.

5.3.5 Speech Audiometry (quiet & noise)

From the speech identification scores (in quiet) in the present study, it is clear that all the subjects had a 100% score in all the ears. There was no difference in SIS of tinnitus and non-tinnitus ear in cases with unilateral tinnitus. In individuals having tinnitus with normal hearing, the speech understanding in quiet is generally not different from non-tinnitus counterpart (Hennig, Costa, Urnau, Becker & Schuster, 2011; Sreeraj, 2017).

In the present study, two subjects reported speech difficulties in noise during case history evaluation. Speech in noise (SPIN) was carried out for only 5 subjects clinically. All the subjects showed normal SPIN scores. In the literature-based protocol, no guideline has recommended speech in noise testing. However, recent findings have shown difficulties in speech in noise and increased listening effort in individuals with tinnitus having normal hearing sensitivity (Degeest, Corthals, Vinck & Keppler, 2014; Denys & Leuven, 2016; Gilles et al., 2016). Based on the clinical findings and evidence-based protocol, SIS in quiet is recommended for all subjects as a part of the

basic audiological evaluation. However, the clinical utility of SPIN is questionable and hence not recommended as a part of clinical assessment protocol.

5.3.6 Uncomfortable level (UCL)

In the present study, the data from UCL revealed that all subjects had normal tolerance limit. People who report tinnitus also report of decreased sound tolerance (DST). Reduced UCL is an important marker for hyperacusis. Only two subjects reported hyperacusis, while findings of UCL suggest that none of the subjects had reduced UCL. All the guidelines recommended the use of UCL for tinnitus assessment. Two guidelines recommended performing UCL testing with caution of DST and history of recent noise exposure (at least 1 week). In the clinical evaluation, UCL was not found as a sensitive test, but the frequent co-occurrence of tinnitus and hyperacusis warrants the need for UCL in the recommended clinical protocol

5.3.7 Immittance Measures: Tympanometry and Acoustic reflex testing

Abnormal tympanogram was not considered in the current study. So, based on the outcome of the study, it is not correct to comment on the inclusion or exclusion of tympanometry. However, several studies have reported tympanometry as an important marker for abnormal middle ear functioning. Hence it can be considered as a tool to identify middle ear disorder as a cause of tinnitus with or without tinnitus

In the clinical protocol, ART was done as part of the basic audiological examination for all subjects. The reflexes were present in all the subjects with tinnitus except for three subjects. The absence of middle ear acoustic reflex alone is inconclusive many times (Gilles et al., 2016). In the evidence-based guidelines, reflexes were recommended by two guidelines (study 1 and study 2). Study 3 did not recommend reflexes citing any diagnostic or counselling importance of results and exposure to unnecessary loud sounds. It can be concluded that acoustic reflex threshold

tests are more reliable when used as part of an audiological test battery rather than on their own. Testing for ART is recommended in the clinical evaluation protocol as a part of basic audiological tests.

RDT was carried out for only 5 subjects, and results were negative for all the subjects. In total, 4 subjects had positive ABR-SOL, but RDT was not available for these subjects. In the evaluation protocol recommended by the literature, RDT is not recommended by any of the guidelines. Moreover, the sensitivity of RDT is reported to be poor (Ambrosetti & Del, 2011). Based on no significant findings in clinical data and evidences from literature, RDT is not recommended as a part of clinical assessment protocol.

5.3.8 Oto Acoustic Emissions (OAE) measures

In the clinical evaluation, TEOAE was administered for 18 subjects. TEOAE was absent in 12 (66.66%) of the 18 subjects bilaterally irrespective of whether tinnitus was unilateral or bilateral (except for 1 subject with unilateral tinnitus showed presence of TEOAE in the non-tinnitus ear). These findings are in accordance with findings of absent TEOAE bilaterally in 50-70% of individuals with tinnitus having normal hearing sensitivity (Dhanya, 2010; Granjeiro et al., 2006)

In the 12 subjects with absent TEOAE, DPOAE was found to be present in 58.33% and absent in 41.67% of subjects. These results are in accordance with previous researchers reporting abnormality of DPOAE in individuals with tinnitus having normal hearing sensitivity (Granjeiro et al., 2006; Paglialonga et al., 2010; Sreeraj, 2017). DPOAE fine structure alterations have also been seen before changes in total DPOAE levels as an early predictor of cochlear disease, according to various studies, fine structure component analysis of DPOAEs could be a feasible method for detecting early changes in cochlear function (Sreeraj, 2017).

The evidence-based assessment protocol has recommended the use of OAE for the assessment of tinnitus. Study 1 has recommended performing TEOAE and DPOAE, especially for individuals with tinnitus having normal hearing sensitivity. Study 3 recommended using DPOAE fine structure from 1 to 10 kHz with 6 to 8 points per octave and suggested that tinnitus pitch usually corresponds to the frequency with poor DPOAE amplitude. In line with the present study, it has been reported that most subjects with tinnitus having normal hearing sensitivity showed abnormality in one of the OAE measures (TEOAE, DPOAE and/or Contralateral suppression OAE) (Dhanya, 2010). Hence it can be concluded that OAE measures are a very important assessment tool in identifying early damage to the cochlea, which is missed by routine audiometry. Contralateral suppression of OAE can help to identify the pathology of the efferent system.

5.3.9 Auditory brainstem response -site of lesion testing (ABR-SOL)

. In the clinical evaluation protocol, ABR-SOL was used only for 9 subjects (B/L tinnitus: 5 & U/L tinnitus: 4). The results were positive for four subjects (Table 4.5). However, Sreeraj (2017) reported that except for Peak I latency, no statistically significant variations was found. The increase in Peak I latency could be attributed to slowed synaptic processes in the organ of Corti or a decrease in neural conduction velocity in the brainstem's first auditory neuron. Findings of a prolonged Peak I but normal Peak V in tinnitus with normal hearing should be related to a hidden hearing loss that manifests as diminished neuronal output from the cochlea and thus wave I of ABR delayed.

In the evidence-based assessment protocol, two studies (study 1 & 2) have recommended ABR- SOL only for subjects with unilateral tinnitus or asymmetrical hearing loss to identify any pathology affecting the auditory nerve. ABR-SOL was not

recommended for bilateral tinnitus. Study 3 has not mentioned about the use of ABR-SOL as a part of clinical evaluation protocol. All guidelines gave strong recommendations against the use of imaging techniques for assessment for tinnitus. Recommendation for MRI was suggested only if ABR-SOL was positive for U/L tinnitus (non-pulsatile tinnitus) or in the case of pulsatile tinnitus. In the present study, out of the four subjects with positive ABR-SOL results. One subject with unilateral tinnitus (absent peak V at high repetition rate) had undergone MRI evaluation. MRI revealed no significant clinical abnormality. Hence the use of ABR-SOL is recommended only for persons with unilateral tinnitus or when RCP is suspected.

5.3.10 Psychoacoustical measures: Tinnitus Matching and Residual Inhibition

In the present study, the psychoacoustical measures were carried out for 12 subjects, and results revealed that the frequency range from 125 to 8000 Hz and loudness from 10 to 65 dBHL was reported. Hébert & Fournier (2017) reported the predominant pitch as 14.64 kHz in normal hearing and 8.5 kHz in the hearing loss group. Sreeraj (2017) reported the mean loudness of tinnitus in normal hearing to be 23.04 dBSL ranging from 5 dBSL to 55 dBSL and frequency range from 125 Hz to 12500 Hz. Generally, the pitch of tinnitus corresponds with the frequency of hearing loss, but that is not the case always. High pitch tinnitus is usually (not always) associated with cochlear pathology and low-pitch tinnitus with conductive pathology. In all three guidelines, psychoacoustical measures were recommended. With reference to findings of various studies, it can be concluded that psychoacoustical measures show a large variability with respect to clinical profile, and these tests are useful for counselling purposes and monitoring change in perceptual characteristics of tinnitus following therapy. Hence these tests are recommended in the protocol for assessment.

5.3.11 Tinnitus Questionnaires

THI was administered for only 1 subject in the present study, and THI indicated moderate tinnitus severity. Based on this, Tinnitus Retraining Therapy (TRT) was recommended as a part of the management plan. All three guidelines recommended the use of specific tinnitus questionnaires for identifying the severity of tinnitus. The presence of bothersome tinnitus and negative reactions to tinnitus or poor Quality of Life (QOL) in individuals with tinnitus warrants the use of some type of validated inventory. Study 1 recommended using a tinnitus grading system and administering tinnitus-related questionnaires to an individual with a grade of 2 or more and making the appropriate referral as required. "Tinnitus Handicap Inventory (THI), Tinnitus Questionnaire (TQ), Tinnitus Reaction Questionnaire (TRQ), Tinnitus Severity Index (TSI), Tinnitus Handicap Questionnaire (THQ), Tinnitus Severity Questionnaire (TSQ) and Tinnitus Functional Index (TFI)" are some of the most commonly utilised surveys (Cima et al., 2019). These methods may also be used to identify patients, identifying those who require extensive rehabilitative management vs those who only require basic counselling. They are also employed in pre-and post-treatment analyses to assess the treatment's efficacy. Hence, using THI or other tinnitus-related questionnaires is recommended in persons who report tinnitus-related distress during case-history evaluation.

5.3.12 Vestibular Assessment

The complaint of vertigo by approximately 50% of the subjects in the present study and the presence of positive history of vestibular conditions like vestibular neuritis, meniere's disease, orthostatic hypotension in the associated conditions highlight the importance of considering vestibular evaluations in individuals with tinnitus reporting vertigo. Similarly, Shulman (1991) has reported that patients with tinnitus have a higher incidence of peripheral vestibular impairment, even when there

is no accompanying vertigo. All three evidence-based guidelines recommended vestibular evaluation using subjective and objective tools whenever vertigo is associated with tinnitus. Hence whenever a vestibular disorder is suspected in an individual, an extensive otoneurological examination is warranted and is recommended as a part of the assessment protocol.

Based on the critical evaluation of the shortcomings of the clinical test battery protocol available from the retrospective analysis and the evidences from the reviewed literature, a clinical evaluation protocol has been proposed. The suggested protocol will help reduce the evaluation inconsistencies (as observed) and equipping the clinician with an effective protocol for diagnosis and appropriate counselling and management of the persons with tinnitus having normal hearing sensitivity.

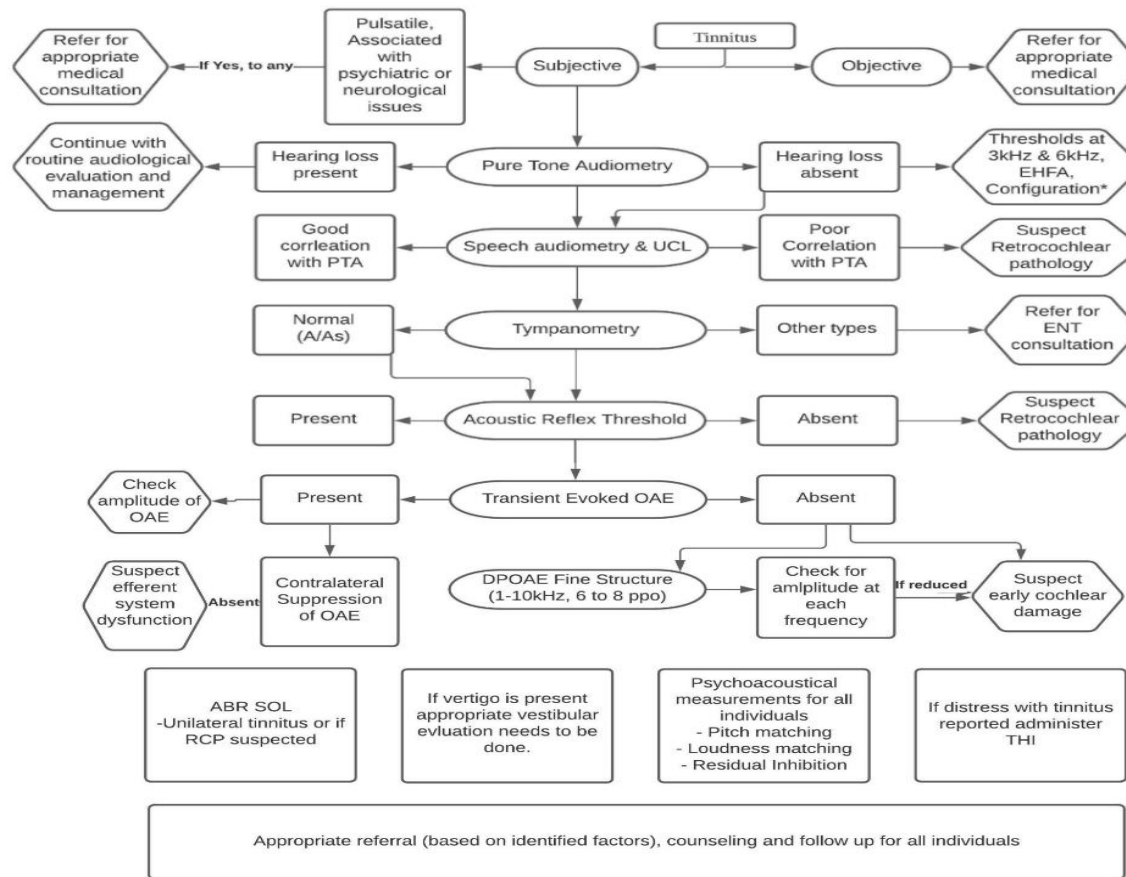
The foundation of effective assessment is laid by a comprehensive case history evaluation. The suggested protocol for case history advocates the use of semi-structured interviews covering factors from various otological and non-otological conditions. Case history also tries to identify persons who require management of tinnitus and associated stress. The semi-structured interview allows the clinician to seek further information for various factors based on a case-to-case basis. The comprehensive case history helps to identify important referral trajectories also.

The audiological tests recommended consisted of basic audiological evaluation, including PTA, speech audiometry, UCL (with caution), and immittance evaluation. The suggested protocol includes various diagnostic tests to identify hidden and sub-clinical pathologies in individuals with tinnitus having normal hearing sensitivity. These tests include identifying hearing thresholds at 3kHz and 6kHz and identifying morphological characteristics from audiogram such as slope, reverse slope and notches, which suggest impaired auditory functioning. EHFA has been suggested for use in all

individuals with tinnitus having normal hearing sensitivity to identify cochlear damage at extended high-frequency range, which will be missed with routine audiometry.

Figure 5.2

Proposed clinical assessment protocol for persons with tinnitus having normal hearing sensitivity.



- Case History (Semi-structured Interview)**
- Demographic details
 - Associated otological complaints
 - Medical and family history:
 - Identification of associated neurological, cardiovascular, otological, psychological, traumatic, metabolic, endocrine mediated and immunological problems.
 - Targeted tinnitus history:
 - Site of tinnitus (U/L, B/L)
 - Origins of tinnitus and its descriptive qualities (pulsatile/non-pulsatile; continuous/intermittent; high pitch/low pitch)
 - Quality of tinnitus (tonal/noise-like)
 - The onset of tinnitus
 - Perception of tinnitus since (acute/chronic).
 - When was tinnitus first noticed & course of tinnitus perception
 - Any factor modulating (aggravating or alleviating) tinnitus
 - The severity of tinnitus perception and its impact on QOL (sleep difficulties, task interruptions, fearful reactions, cognitive-attentional problems, negative affect).
 - Long-term pharmaceutical usage; drug history/medications
 - Relevant personal history, leisure activities/hobbies leading to noise exposure, and recent life events

Tests such as TEOAE are an objective indicator of cochlear damage. Based on findings from the clinical data (absent TEOAE in many subjects) and evidence from literature, TEOAE has been recommended. If TEOAE is absent, DPOAE Fine structure from 1 to 10 kHz with 6 to 8 points per octave has been recommended. Absent DPOAE or reduced amplitude will provide evidence for early cochlear damage. In case TEOAE is present amplitude of TEOAE should be analysed. Reduced amplitude can be interpreted as early cochlear damage. In case of normal amplitude or robust TEOAE, contralateral suppression of TEOAE should be carried-out for identifying efferent system dysfunction.

ABR-SOL is recommended only for persons with unilateral tinnitus and/or suspected Retro Cochlear Pathology (RCP). For bilateral tinnitus cases, ABR-SOL is not recommended on the basis of no significant clinical findings found and no evidences from literature justifying the need for the use of ABR in such individuals. This help in increasing the time-efficiency and cost-effectiveness of the suggested protocol. However, in case of suspicion for RCP, ABR-SOL should be used as a part of the clinical test battery protocol.

Psychoacoustical measurements are recommended for all individuals with tinnitus, which includes pitch-matching, loudness-matching and residual inhibition. These tests help in understanding the characteristics of tinnitus perception. The most important use of these factors is for counselling and management purposes rather than adding to the diagnostic value.

Vestibular evaluation is recommended for the persons reporting vestibular problems during case history evaluation. The presence of vestibular problems in 50% of subjects highlights the need for specifically inquiring about vestibular evaluation during case history. For persons reporting distress or difficulties with tinnitus, administering THI is strongly recommended to decide on appropriate referral and management. Appropriate referral for all the identified associated conditions is a must. With the help of the suggested protocol, effective counselling and management options can be provided to individuals with tinnitus having normal hearing sensitivity.

Chapter 6

SUMMARY AND CONCLUSION

Tinnitus is a prevalent phenomenon affecting nearly fifteen percent of the population. Being a subjective phenomenon and associated with multiple conditions, tinnitus has many forms. Tinnitus with normal hearing sensitivity is a clinical challenge and is associated with heterogeneity in the clinical profile. Recent findings have suggested that tinnitus with normal hearing sensitivity is likely to indicate underlying impairment in cochlear or neural functioning at various auditory levels and might be indicative of a hidden and subclinical otological problem. Various tests have been recommended in the literature that can be used to assess tinnitus, especially in normal hearing individuals. However, the clinical use of such tests is limited. Hence the present study was undertaken for identifying the clinical evaluation protocol commonly used at the institution level and compare it with the available literature for effective assessment of individuals with tinnitus having normal hearing sensitivity. Identifying the shortcomings and proposing a clinical evaluation protocol for the assessment of individuals with tinnitus having normal hearing was the major objective of the study. To collect information about demographic details, associated symptoms with tinnitus and audiological tests carried out, and their findings to know the common protocol used for the clinical assessment. The present study was carried out in two phases. Phase I included retrospective analysis of case files. Phase II consisted of extracting assessment protocol from literature.

The clinical test battery for assessment included case history interview, ENT evaluation, various tests such as PTA, speech audiometry, SPIN, UCL, immittance evaluation, OAE, ABR-SOL and tinnitus matching. However, there was

inconsistency in the use of test battery for all individuals. There was a large amount of heterogeneity in clinical signs and symptoms. Based on the clinical findings and evidences from the literature, a protocol for assessment was recommended. The recommended clinical protocol included comprehensive semi-structured case history evaluation with special emphasis on a targeted tinnitus history identifying various associated (otological & non-otological) conditions and identifying the impact of tinnitus on QOL, followed by ENT examination. The audiological test battery consisted of PTA, EHFA, speech audiometry, UCL, tympanometry, ART, TEOAE, DPOAE fine structure and ABR-SOL(for U/L tinnitus only). Psychoacoustical measurements including pitch matching, loudness matching and residual inhibition have been recommended for counselling perspective. Administering THI was also recommended for persons who reported distress with tinnitus. Appropriate referral should be recommended based on identified factors during case history evaluation. The suggested protocol for assessing individuals with subjective tinnitus having normal hearing sensitivity and bridges the gap from research to clinical practice.

6.1 Clinical implications

There are several clinically significant implications of the study. The first contribution of the study is that it provides empirical data to highlight the test battery approach for individuals having tinnitus with hearing sensitivity within normal limits. This will help in bringing uniformity and the use of appropriate diagnostic tools for such individuals.

Second, the tinnitus assessment protocol provides a streamlined flow for clinical evaluation of these individuals based on evidence from various high-quality

research articles. It can be easily incorporated into the standard clinical practice. Leading to appropriate diagnosis and management of such individuals.

Third, noticing the consistent increase in the prevalence of individuals with normal hearing sensitivity having tinnitus, this protocol addresses not only on assessment but also for providing appropriate referral and counselling.

6.2 Limitations

This study had some limitations. First, amid pandemic follow-up with patients regarding the present status of their problem could not be done. Second, the data collected did not include the vestibular assessment findings of the individuals. Third, as it is a retrospective analysis, the reliability of the information recorded could be questionable. Finally, smaller sample size was considered for the study, which could have affected the outcomes.

6.3 Future Research

Standardizing the proposed protocol for individuals with tinnitus and hearing sensitivity within normal limits could provide insight into further modifications to the protocol (although there has been extensive research on this topic, no major breakthrough is achieved). Research on various associated factors with tinnitus, specifically in individuals with normal hearing sensitivity, would fetch us a detailed list of factors responsible for the perception of tinnitus, And the research on interactions of these factors in individuals experiencing tinnitus would give an idea about how they influence the course and distress associated with tinnitus. Future research in the above-mentioned domains would help to provide the best possible care for his/her patients.

To better understand the etiology, pathophysiology and role of various factors leading to distress with tinnitus in a larger sample size is suggested for future research.

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